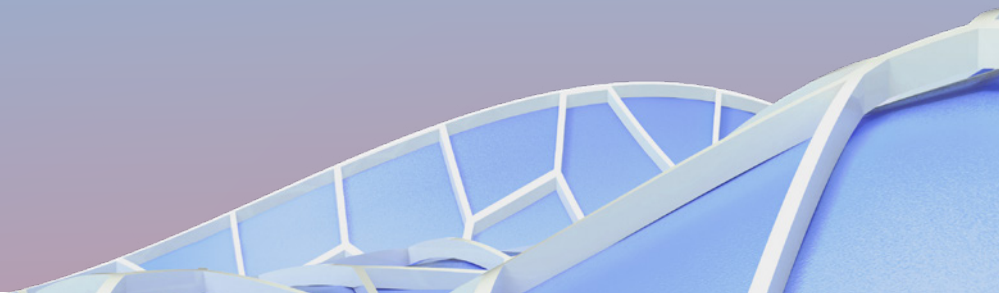
Strategic risk signals

How life sciences leaders stay ahead of disputes in Australia

MinterEllison.

Contents



Foreword

Professor Bruce Robinson AC

Disputes between parties in the life sciences sector are increasing.

The size of the Australian life sciences sector is small compared with our US and European counterparts, in part because of the poor commercialisation record of Australian universities and the lack of long-term capital willing to support early-stage work through to commercialisation. The lack of a clear, reliable and well-trodden path creates fertile ground for disputes, since expectations and the path to them often vary.

Professor Bruce Robinson is a renowned physician, academic, and advisor with over 25 years' experience as a leader in healthcare. In addition to being a highly experienced practising endocrinologist, Professor Robinson AC currently serves on the boards of major listed healthcare entities. He is Chair of Mayne Pharma Group Limited and a Non-Executive Director of Cochlear Limited and Healius. He is also a Non-Executive Director of British speciality pharmaceutical company CS Pharmaceuticals Ltd and an advisor to MinterEllison.

Professor Robinson's former roles include Chair of the Australian Government's taskforce of expert clinicians charged with reviewing the Medicare Benefits Schedule, the Medical Benefits Schedule Review Taskforce, and chair of Australia's peak advisory and funding body for medical research, the National Health and Medical Research Council. He is a former Dean of the University of Sydney's Medical School, the former head of the Cancer Genetics Unit at the Kolling Institute, Royal North Shore Hospital, and the former Head, Division of Medicine, Royal North Shore Hospital.

Professor Robinson was awarded a Doctor of Medicine from the University of Sydney in 1990, having earlier undertaken a fellowship at Harvard Medical School and graduated from the University of Sydney with a Master of Science degree. Professor Robinson is a Fellow of the Australian Institute of Company Directors.

A critical factor in avoiding disputes at this early-stage is a clear understanding of intellectual property ownership between investors, students and universities, and agreement on the intended path to commercialisation. Once funding becomes available, the use of that funding, milestones and the future pipeline of capital all need to be very clear to avoid disagreement. The role of the board, founders and senior management in any start up needs to be clear, and, where companies become publicly listed, the role of all participants in the stewardship of investor capital needs to be even more clearly spelled out.

These early-stage tensions, however, are only part of the picture. As life sciences organisations scale, partner globally and operate in increasingly regulated and data-driven environments, the disputes landscape broadens considerably. In Australia, the role of regulators such as ASIC and the TGA continues to expand, and disputes with these entities can become costly and distracting for all concerned. These regulatory pressures sit alongside other sources of conflict arising across the sector, including intellectual property disputes, product liability claims, class actions and the increasing influence of technology, including AI, across the life sciences landscape. Together, these forces are reshaping how and when disputes emerge, and the speed at which they can escalate.

It is against this backdrop that this report considers dispute activity across the Australian life sciences landscape, with a focus on the trends, pressure points and risk pathways most relevant to those responsible for investment, governance and commercial decision making. Time spent preparing strategy, being familiar with rules and regulations, and being advised by those who have been down these paths previously, will be rewarded.

There have been few truly global biotech success stories from Australia; CSL, Cochlear and ResMed remain the best recognised. Each had financial support from investors and government grants. Unlike in other jurisdictions, such as the UK, the Commonwealth has not taken shareholder stakes in these companies. While this may create certain complications, it would surely help biotech startups to get to commercialisation and as an experienced partner, could help prevent some disputes from arising in the first place.

Ultimately, we need a national supportive strategy for the life sciences sector to smooth the path to commercialisation and provide investors with greater confidence in making critical investments in the sector.

Executive summary

The Australian life sciences sector is entering a period of heightened legal and regulatory complexity.

The accelerating pace of change in scientific innovation, expanding regulatory oversight and the growing use of digital technologies are reshaping how disputes arise and how organisations manage legal risk.

Historically, disputes in the life sciences sector were often concentrated in areas such as patent litigation and product liability claims. While those risks remain significant, organisations are now facing a broader and more interconnected dispute landscape. Regulatory investigations, data governance issues, cybersecurity incidents and the deployment of emerging technologies such as artificial intelligence (AI) are increasingly giving rise to complex disputes involving multiple legal frameworks.

In tandem, regulators in Australia are demonstrating a greater willingness to pursue enforcement action in areas affecting the sector. Developments in relation to privacy and therapeutic goods laws and regulations and an enhanced focus on consumer protection are contributing to a more active regulatory environment, in which compliance failures may result in both regulatory proceedings and civil litigation.

Technological innovation is also reshaping the dispute landscape. AI, digital health platforms and data-driven research are transforming the way life sciences organisations develop products and deliver healthcare solutions. However, these technologies also introduce new legal questions relating to intellectual property, privacy, regulatory classification and liability.

Against this backdrop, several key trends are emerging across the life sciences sector:

- **increasing regulatory enforcement** in areas affecting patient safety, advertising, data governance and emerging technologies;
- **growing litigation risk** associated with the handling of sensitive health information and large-scale data ecosystems;
- **evolving intellectual property challenges** arising from the use of AI in research and development; and
- **greater financial exposure from disputes** where insurance coverage does not align with emerging operational risks.

For life sciences organisations, these developments highlight the importance of proactive governance and dispute preparedness. Many disputes arise from operational or regulatory issues that escalate before legal risks are fully assessed. Organisations that establish clear governance frameworks, integrate legal oversight into technology deployment and regularly review their regulatory and insurance strategies are better positioned to manage these risks.

Looking ahead, disputes in the life sciences sector are likely to become increasingly complex, cross-border in nature and closely intertwined with regulatory oversight. As innovation accelerates, organisations will need to ensure that governance, compliance and risk management frameworks evolve at the same pace as scientific and technological change.

For organisations operating at the intersection of healthcare, technology and regulation, effective dispute readiness will increasingly become a core strategic capability rather than a reactive legal function.

Insights from health and life sciences leaders

Method

In May 2026, MinterEllison surveyed more than 50 Australian health and life sciences leaders, including General Counsels and company owners to capture their perspectives on class actions risks, sensitive health data, privacy compliance, the use of AI and AI governance and regulatory concerns.

The survey was multiple-choice with some free text options. The anonymised results were pooled and analysed. Survey findings were supplemented by our own market intelligence and review of relevant public sources, case law and regulatory developments.

Key insights are summarised on this page and feature throughout the report.

Demographics

95%
of leaders surveyed are aged 35-54 years

91%
of leaders surveyed are General Counsels

7%
are company owners

2%
are CEOs

Key insights

Rising class action exposure is being felt by leaders.

79%
expect class action exposure to increase over the next 3–5 years.

Confidence in responding to a class action is high, but preparedness is uneven.

69%
report high or very high confidence in responding to a major class action.

32%
have material readiness gaps.

Class action drivers: Product liability leads, but the risk mix is broadening.

Anticipated class action drivers include:

Risk type*	%
Product liability	60%
Misleading or deceptive conduct / misrepresentation	53%
Regulatory-driven follow-on class actions	49%
Data privacy / cyber-related class actions	46%
Personal injury	32%
ESG-related class actions	21%
Shareholder / securities class actions	11%
Employment-related class actions	7%

**multi-select response*

Key insights

Privacy and regulatory scrutiny are core concerns.

75%

are at least moderately concerned about increased OAIC scrutiny.

Regulatory and **data/privacy/cyber** are tied as the top perceived legal vulnerabilities.

When asked whether their organisation had established formal governance frameworks or policies across key AI risk areas, respondents reported the strongest coverage for product safety and privacy.

Governance is notably less developed across AI bias and ethics, regulatory risk, workforce capability and human oversight, and third-party and vendor AI risk.

AI risk area*	Yes	Working on it	No
Product safety and quality	**81%**	7%	12%
Data, privacy and confidentiality	**72%**	5%	23%
IP and data ownership	**70%**	19%	11%
Decision-making and liability	**61%**	26%	12%
Operational use and misuse	**54%**	26%	19%
Governance and organisational readiness	49%	**33%**	18%
Bias, ethics and regulatory	44%	**39%**	18%
Workforce capability and human oversight	40%	**37%**	23%
Third party / vendor / supply chain AI	40%	**33%**	26%

**multi-select response*

There is strong support for IP reform and genuine industry debate around how to balance innovation incentives with generic and biosimilar market access.

Statement*	Yes	No	Unsure
Reform is necessary for timely resolution of IP disputes	**81%**	18%	2%
Australia would benefit from an Orange Book patent linkage system	**74%**	18%	9%
PBS reform to restore prices on patent infringement finding	**70%**	11%	19%
Legislated first mover advantage for generic entrants	51%	33%	16%

**multi-select response*

Part I – Disputes reshaping the life sciences sector

A number of dispute trends are already reshaping the Australian life sciences sector.

The following chapters examine the most significant developments affecting pharmaceutical, biotechnology and medical device organisations.

1.1 Class actions in life sciences

The billion-dollar question: preparing Australian life sciences organisations for class actions.

Lead author:
David Taylor, Partner

"Australian life sciences organisations should not treat US developments as merely cautionary tales from abroad – but rather as immediate and material risks to their own operations."

David Taylor

Chapter summary

Class actions are becoming an increasingly important feature of the disputes landscape for life sciences organisations operating in Australia. Developments in US product liability litigation often act as an early indicator of the types of claims that may later be pursued in Australian courts.

For pharmaceutical, biotechnology and medical device organisations, this creates a material strategic risk. Even where claims are defensible, the cost, complexity and reputational impact of large-scale litigation can be significant. The issue is not simply whether an organisation can defend a claim, but whether it is prepared for the commercial and operational consequences of large-scale litigation.

Drawing on recent US and Australian proceedings, this chapter examines emerging litigation patterns and highlights the key issues life sciences organisations should be considering now to strengthen preparedness and manage class action exposure.

Introduction

The life sciences and pharmaceutical industry has long been a focal point for product liability litigation and class actions, particularly in the United States, where billion-dollar settlements are now increasingly common. The success achieved by US plaintiffs has prompted Australian class action promoters to assess whether analogous claims can be viably pursued in this jurisdiction. This trend has driven a marked increase in life sciences product liability class actions filed in Australian courts – involving the same or substantially similar products that were the subject of US proceedings – a phenomenon commonly referred to as 'copycat' litigation.

Australia is an attractive jurisdiction for class action promoters. The Australian class action landscape has matured considerably since its inception in 1992 – driven principally by the increasing sophistication of plaintiff law firms, the proliferation of third-party litigation funding, and the demonstrated willingness of Australian courts to adjudicate, and provide vindication for plaintiffs in, among others, complex product liability class actions. The threshold requirements to bring a class action in Australia are low, and, unlike in the US, there is no 'class certification' procedure. This means that once a class action is filed in Australia, it is extremely difficult for a defendant to stop it at an early stage compared to the US.

As a result of these factors, Australia is now commonly stated to be the second most active class action jurisdiction globally, behind only the US.[1]

As Australian class action promoters increasingly consider the viability of filing domestic claims in respect of pharmaceutical products distributed across multiple jurisdictions, a thorough understanding of the current US life sciences litigation landscape is essential for Australian organisations seeking to protect their commercial interests and reputation. Australian life sciences organisations should not treat US developments as merely cautionary tales from abroad – but rather as immediate and material risks to their own operations.

79% of the healthcare leaders surveyed expect their class action exposure to increase over the next 3-5 years.

When asked to describe their organisation's current approach to class action risk:

- **46%** have a formal class action risk framework.
- **16%** have regular board-level reporting on class action exposure.
- **24%** have dedicated internal capability/playbooks or some proactive identification.
- **14%** are primarily reactive.

72% of surveyed leaders have formal or cross-functional governance in place.

12% use proactive horizon scanning with legal input.

16% have informal/inconsistent escalation thresholds or monitor primarily to meet minimum regulatory requirements.

Current US life sciences litigation landscape and trends

The US's multi-district litigation (**MDL**) procedure consolidates civil cases raising common factual questions into a single court for coordinated pre-trial proceedings. This mechanism enables the rapid aggregation of thousands of claims into a single large-scale consolidated proceeding, generating extensive discovery obligations, protracted and costly expert disputes, and complex settlement dynamics – often driven by the sheer volume of individual claims, cumulative defence costs and the inherent risks of litigation and trial.

Multi-district litigation is a US federal procedure consolidating similar claims before one judge for pre-trial purposes.

CASE STUDY

Zantac multi-district litigation – the cost of mass pharmaceutical litigation

The Zantac MDL illustrates the substantial financial and temporal burden that large-scale pharmaceutical litigation can impose on defendants, irrespective of the ultimate outcome.

In litigation commenced against the manufacturers of Zantac, plaintiffs alleged that ranitidine – the active ingredient in the widely prescribed heartburn medication – could degrade into N-Nitrosodimethylamine (NDMA), a probable human carcinogen.

The proceedings were consolidated into multi-district litigation in the US involving numerous manufacturers and distributors.

After approximately four years of litigation, the MDL[2] was dismissed on the basis that the plaintiffs failed to establish general causation. By that stage, however, the defendants had incurred substantial legal costs – estimated in the millions of dollars – and sustained significant reputational harm, a consequence that the Court itself acknowledged. The case illustrates that even a favourable outcome on the merits may nonetheless result in material financial exposure and lasting reputational consequences for defendant organisations, their directors and senior executives.[3]

LESSON

Even successful defendants can incur substantial litigation costs and reputational harm.

While that is practically speaking the best outcome that a defendant in a US class action can achieve, in contrast unsuccessful defendants are exposed to not only the direct costs of litigation, but contagion risks that can spread even to overseas jurisdictions.

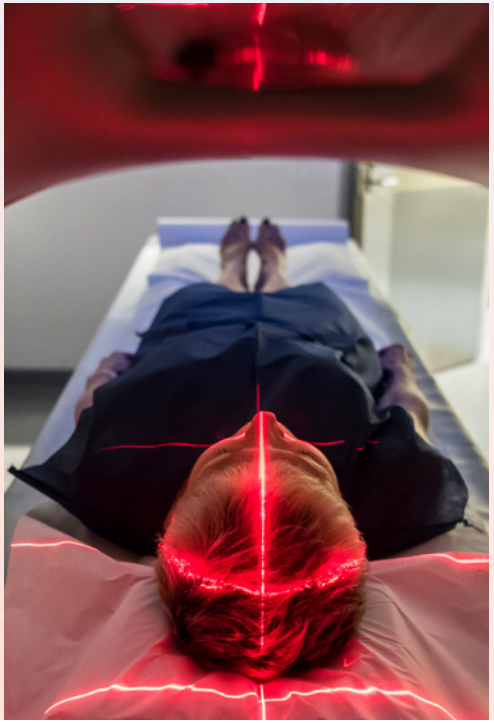
The following examples illustrate instances in which defendants to US product liability proceedings were unsuccessful, with the resulting litigation momentum extending to claims commenced in Australia:

- **In the 'Roundup' litigation against Bayer** (following its acquisition of Monsanto), early plaintiff verdicts in 2018–2019 – including in *Johnson*,[4] *Hardeman*[5] and *Pilliod*[6] – generated powerful litigation momentum. Throughout the litigation, Bayer consistently denied that its products caused cancer[7] relying, among other things, on findings by the US Environmental Protection Agency (**EPA**) and regulatory agencies across Europe and Asia that no scientific link had been established between glyphosate and non-Hodgkin lymphoma.[8]

  Notwithstanding this body of regulatory and scientific evidence, Bayer ultimately agreed to pay a US$10 billion settlement to resolve approximately 100,000 similar claims.[9] Following this settlement, a class action was commenced in the Federal Court of Australia that made similar allegations in respect of Roundup.

- **In the talc products litigation against Johnson & Johnson** – the earliest proceedings having commenced in 2009 – approximately 65,000 plaintiffs alleged that Johnson & Johnson's talc-based products possessed carcinogenic properties causing ovarian cancer, with subsequent claims also alleging asbestos contamination causing ovarian cancer or mesothelioma.[10] This was the largest MDL in the US. Significant plaintiff verdicts, including awards of US$18 million and US$22 million as recently as December 2025,[11] generated sustained pressure on Johnson & Johnson. These outcomes were reached notwithstanding Johnson & Johnson's reliance on evidence and reports from the US Food and Drug Administration (**FDA**) concluding that no asbestos had been detected in any talc samples.[12] Following this momentum, a class action was filed in the Supreme Court of Victoria advancing similar allegations against Johnson & Johnson.

> *"Mass-tort class actions follow a repeatable pattern – once plaintiffs achieve early success, claims proliferate quickly and the litigation spreads across jurisdictions."*
>
> David Taylor



Australia's established reputation as a favourable forum for representative proceedings makes it a natural destination for the transposition of these claims. Critically, the success of claims grounded in negligence or the consumer protection provisions of the Australian Consumer Law (**ACL**) turns on establishing substantially similar elements required to prove similar US causes of action. The doctrinal parallels are particularly evident when comparing a US failure-to-warn claim with an Australian claim for misleading or deceptive conduct under s 18 of the ACL.

In the US, a failure-to-warn claim requires the plaintiff to establish that the product warnings were inadequate, that the inadequacy was a proximate cause of injury, and that the plaintiff suffered actual compensable harm – with questions of loss and damage informed by expert evidence as to the risks known at the relevant time and whether adequate disclosure would have altered consumer behaviour.[13]

In Australia, the same facts can be readily re-characterised as a claim under section 18 of the ACL – for instance, by pleading that express representations concerning known risks in marketing and packaging materials (or, equally, the omission of material information from them) conveyed a misleading or deceptive representation as to the safety profile of the product to the ordinary and reasonable consumer. The causation inquiry on loss is similarly congruent: the plaintiff must demonstrate that the consumer would not have purchased or used the product, or would have done so on materially different terms, had the true risk profile been disclosed. The Johnson & Johnson talcum powder litigation mentioned earlier – presently on foot in the Supreme Court of Victoria – provides an instructive illustration of how a US case theory can be transposed into an Australian ACL claim with minimal reformulation.[14]

Most life sciences organisations adopt a consistent global approach to product design decisions, risk and safety communications, adverse event monitoring and internal responses to emerging risks. Given the global alignment – and the relative ease with which US case theories can be copied, transferred and adapted into an Australian cause of action – any pharmaceutical product that is sold globally (including in Australia) may be exposed to copycat litigation.

We explore in further detail two case studies involving successful proceedings commenced against manufacturers of surgical pelvic mesh and hip/joint implant replacements in the US, and which have already been replicated in Australia.

The majority of healthcare leaders surveyed believe they are prepared, but a first major action could expose significant gaps.

- **69%** report high or very high confidence their organisation could effectively prevent, respond to and manage a major class action today.
- **28%** are moderately confident but have untested processes.
- **4%** report low confidence due to no consistent approach.

When describing their organisation's approach to class action risk:

- **46%** have a formal class action risk framework.
- **24%** are proactive but informal.
- **14%** are primarily reactive.

CASE STUDY

Pelvic mesh litigation – crystallised class action risk in Australia resulting in a A$300 million settlement.

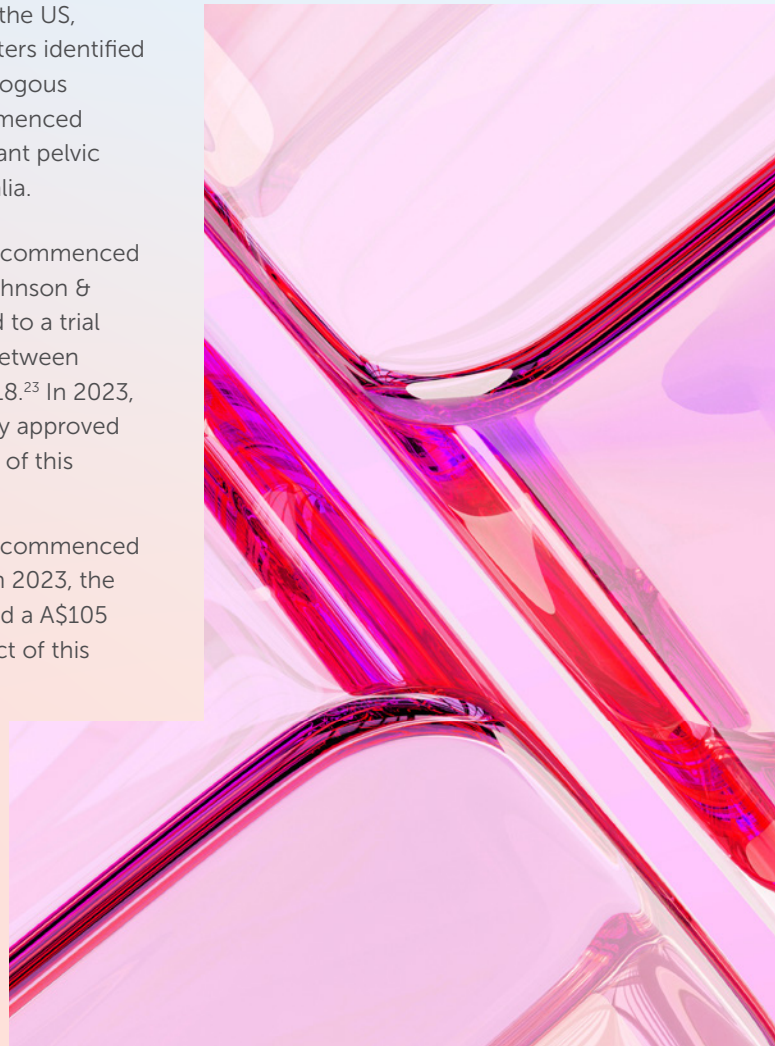
Transvaginal and pelvic mesh litigation represents one of the most instructive examples of how product liability risk in the life sciences sector can crystallise into large-scale, high-value class action exposure across multiple jurisdictions.

The first pelvic mesh case was filed in approximately 2009 in the US,[15] and in 2012,[16] MDLs consolidated similar claims against American Medical Systems,[17] Ethicon,[18] and Boston Scientific[19] (among others) yielding the following significant outcomes for plaintiffs:

- **American Medical Systems:** aggregate settlement payments exceeding US$2.6 billion to plaintiffs in the US.[20]
- **Ethicon:** a US$120 million jury award (the largest single Ethicon mesh verdict), a US$117 million settlement with 41 states and the District of Columbia, and a US$302 million judgment in favour of the State of California in a parallel proceeding to the MDLs.[21]
- **Boston Scientific:** aggregate settlement payments exceeding US$400 million to plaintiffs in the US.[22]

Following these outcomes in the US, Australian class action promoters identified an opportunity to pursue analogous claims domestically and commenced proceedings against the relevant pelvic mesh manufacturers in Australia.

- In 2012, a class action was commenced against Ethicon Sarl and Johnson & Johnson, which proceeded to a trial spanning several months between July 2017 and February 2018.[23] In 2023, the Federal Court ultimately approved a A$300 million settlement of this class action.[24]
- In 2021, a class action was commenced against Boston Scientific. In 2023, the Federal Court also approved a A$105 million settlement in respect of this class action.

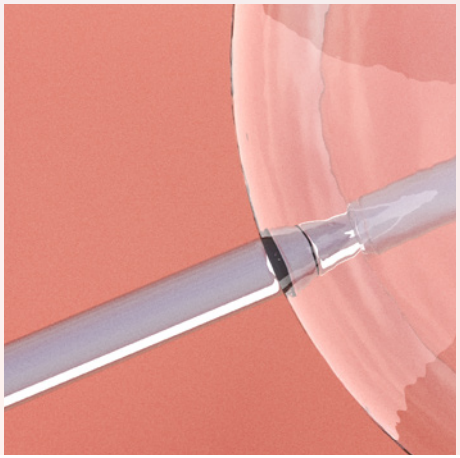


LESSON

Successful US product liability litigation can quickly translate into Australian class action exposure.

"Given the global approach to product design, communications and marketing, the risks that exist in US litigation can be readily adapted into an Australian cause of action."

David Taylor



These Australian class actions demonstrate that mass-tort proceedings originating in the US are both viable and replicable in Australia – owing principally to the substantial overlap between the relevant legal frameworks, the transferability of causation theories, and the availability of third-party litigation funding – with significant settlement sums awarded to group members (and, in the case of Boston Scientific, within a comparatively short timeframe). Importantly, the lessons from the Australian pelvic mesh class actions extend well beyond the manufacturers of implantable devices. Australian class action promoters actively monitor the US litigation landscape and may elect to commence a class action in respect of any pharmaceutical product sold in Australia where material similarities exist – for example, in manufacturing processes, manner of use, packaging or marketing – compared to the matters that are the subject of the US proceedings.

Specifically, in the Australian pelvic mesh class action, the Court held that pre and post-market evaluation of the Ethicon mesh devices were insufficient to discharge Ethicon's duty of care, and that, had Ethicon disclosed the pleaded risks, the applicant would not have consented to implantation of the device.

The pelvic mesh case study shows how quickly class action risk can emerge, increase in scale and ultimately result in significant settlement sums for Australian life sciences organisations. It reinforces the need for all organisations, their directors and senior executives to assume that product design decisions, safety communications, adverse event monitoring and internal responses to emerging risks may be the subject of an Australian class action.

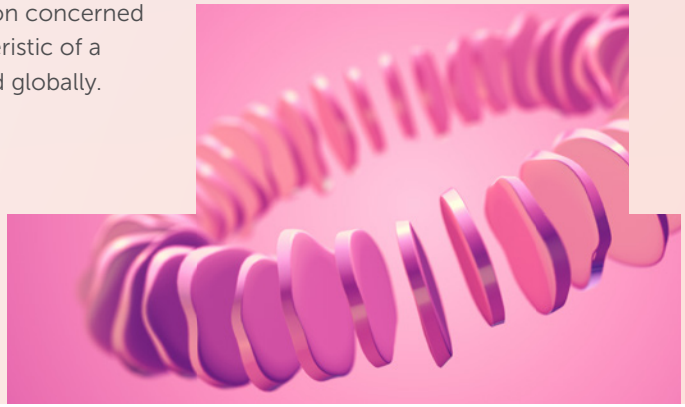
CASE STUDY

DePuy Hip Implant litigation – Australian class action proceedings filed off the back of successful litigation in the US, resulting in a A$250 million settlement.

The DePuy hip implant MDLs provide a clear illustration of how large-scale US medical-device litigation can migrate to Australia with relatively little friction. In re *DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*,[25] the plaintiffs alleged that a design flaw in a hip implant caused a condition called *metallosis*, which destroyed bone, muscle and other tissue. The causation theory was readily transferable across jurisdictions, as the allegation concerned an inherent design characteristic of a product that was distributed globally.

The initial US trial resulted in a US$502 million verdict for the plaintiffs (which was ultimately reduced to US$245 million following multiple appeals).[26] The plaintiffs' causation arguments centred on design defects, supported by epidemiology expert evidence and internal design documents. The plaintiffs effectively contended that the design in question presented an avoidable risk, given the availability of safer alternative designs.[27]

The verdict subsequently enabled settlements totalling over US$4 billion across approximately 20,000 related claims, together with a global recall of DePuy's ASR hip implant products in 2010.[28]



Following these developments, an Australian Federal Court class action concerning hip implants was commenced in 2011 against DePuy International Ltd, which manufactured the DePuy ASR hip implants, and Johnson & Johnson, which distributed and sold the implants in Australia.[29] The class action settled in 2016 for A$250 million. Though the claims were never tested at trial, the plaintiffs advanced very similar causation arguments to those raised in the US MDLs, indicating that the US claims were capable of translation into Australian causes of action without significant re-formulation – specifically, claims in negligence and under the consumer protection provisions of the *Trade Practices Act 1974 (Cth)* and the ACL (in particular, the provisions relating to defective goods and misleading or deceptive conduct).

The DePuy hip implant litigation not only illustrates the speed at which a defective product claim in the US can be brought over into Australia (similar to the pelvic mesh case study), but it also highlights the fact that international participants are not immune to Australian class action risk. In Australia, the DePuy hip implant claim was brought against the UK-based manufacturer, as well as the Australian supplier of that product (J&J), with little to no re-formulation of the initial claim. This is because the operation of the ACL is far-reaching and applies to foreign entities – regardless of their place of incorporation – as long as that entity supplies goods or services to a consumer based in Australia. Specifically, Australia's High Court held that foreign entities carrying on business in Australia are subject to the ACL even if their contracts with consumers are governed by foreign law, and even if services are to be delivered wholly outside of Australia.[30]

LESSON

US litigation outcomes often serve as early warning indicators for Australian class action risk.

"In our experience, Australian class action promoters regard these developments as favourable indicators and will accordingly accelerate their due diligence and book-building efforts in respect of commencing analogous proceedings in Australian courts."

David Taylor

For Australian life sciences organisations, the experience of pelvic mesh and DePuy demonstrates that US MDLs should be considered upstream risk indicators. Once an adverse judicial finding on defect or the relevant science is made in the US, it's likely to materially reduce the risk and uncertainty for a plaintiff law firm or litigation funder associated with bringing an analogous class action in Australia.

That is particularly the case with the growth of international litigation funders who seek to duplicate a successful case strategy that they have funded in one jurisdiction (such as the US) in another (such as Australia), utilising the learnings and evidence that they have already invested in for further successful returns.

Key lessons for Australian life sciences organisations

Australian life sciences organisations now face materially heightened class action exposure. The demonstrated pattern of successful US litigation catalysing analogous claims in Australia represents a tangible and escalating risk. The above examples show that notwithstanding legitimate and well-developed arguments contesting the relevant scientific and causation issues, the sustained commercial and reputational pressures generated by the scale, cost and duration of large class action proceedings often outweigh the theoretical strength of a defendant's position on the science or the law. This pressure often leads to a defendant choosing to pay a significant settlement sum to compromise the litigation, even if a defendant's case is arguable and far from hopeless.

As outlined above, recent class action trends in US product liability litigation frequently operate as a leading indicator of emerging risk for Australian organisations – particularly where the product in question (or its generic equivalent) is already supplied domestically. There is no lack of products that have faced litigation in the US but are or have also been distributed in Australia. For example, proceedings concerning:

- allegations of a failure to disclose fungal contamination in lubricant eye drops;[31]
- semaglutide injection, alleging a failure to warn of the risks of gastroparesis and other serious adverse events allegedly associated with the product, including gastrointestinal injuries, ischaemic bowel, necrotising pancreatitis, gallbladder disease, deep vein thrombosis, micronutrient deficiencies, Wernicke's encephalopathy and aspiration of gastric contents;[32]

- in respect of antifungal spray products, alleging that the relevant manufacturers failed to disclose the presence of dangerous levels of benzene (a known human carcinogen) in the products;[33]
- teprotumumab injection, indicated for the treatment of thyroid eye disease, alleging inadequate pre-market testing and a failure to warn prescribers and patients of the known risk of adverse effects, including permanent hearing loss and tinnitus;[34] and
- infant formulas, alleging a failure to warn that cow's milk-based formulations could cause, or materially increase the risk of, necrotising enterocolitis – a severe and potentially fatal gastrointestinal condition – in premature babies.[35]

Against this backdrop, prudent directors and senior executives should systematically assess their class action exposure across all products, evaluate the likelihood that proceedings may be commenced in the near term, and take proactive steps to prepare well in advance.

The US experience with pelvic mesh and hip implant litigation yields several instructive lessons for Australian life sciences organisations:

- class action risk may crystallise years after product launch, underscoring the necessity of robust and ongoing post-market surveillance (pharmacovigilance) – in particular, the timeliness and rigour of signal detection (being the systematic identification of potential new safety risks associated with authorised drugs or medical devices) and the adequacy of escalation protocols;
- once a potential safety signal is identified, timely and consistent communication of risk is critical – encompassing both the speed with which organisations respond to emerging data and the degree to which risk communications are harmonised across jurisdictions and markets; and
- despite legitimate arguments about the relevant science and causation issues, the costs to defendant organisations (being financial and reputational) in defending a class action are significant – regardless of the outcome.

The strategic imperative is accordingly not retrospective compliance, but forward-looking preparedness.
This requires more than formulating a defence strategy once proceedings are threatened or on foot. Rather, organisations should proactively embed robust governance, data management, scientific and communications frameworks into their day-to-day operations, implement rigorous documentation and risk-management procedures, and consider the adequacy of, and potentially update their insurance requirements, to anticipate and prepare for potential class action exposure well before any claim is foreshadowed or commenced.

Organisations should also actively monitor emerging safety signals and treat them not merely as regulatory compliance obligations, but as matters warranting rapid, cross-functional escalation across the business.

In particular, medical affairs, regulatory, legal and commercial teams should each participate in the risk management process and develop structured, contemporaneous decision memoranda that record, among other things, the rationale underpinning risk assessments, the basis for labelling updates or the decision to maintain existing warnings, and the justification for any planned post-market studies or ongoing surveillance.

Product information and consumer-facing materials should be updated promptly whenever the risk profile materially changes. As international organisations become increasingly complex and are necessarily divided – and staffed – into different regions (e.g. Asia, EMEA, US), organisations must remember to implement and deploy these strategies at a global level and as part of a cohesive framework.
It is critical to ensure that risk events and knowledge of such events are shared globally within the organisation's legal and commercial teams as soon as they emerge, to proactively manage their class action risk.

> *"The strategic imperative is accordingly not retrospective compliance, but forward-looking preparedness."*
>
> **David Taylor**

Practical guidance: Class action preparedness checklist

The following checklist synthesises the lessons learnt from the US experience into some proposed actionable steps and is intended to assist Australian life sciences organisations in managing – and, where possible, mitigating – their heightened exposure to class action risk.

Risk domain	Key actions	Implementation priority
Pharmacovigilance	■ Implement post-market surveillance across all jurisdictions ■ Promptly evaluate overseas safety signals ■ Comprehensively review and document safety processes ■ Review scientific publications for safety concerns	High
Product information	■ Conduct regular Consumer Medicine Information and Product Information (CMI/PI) reviews ■ Monitor overseas regulatory actions ■ Engage proactively with the TGA on labelling updates ■ Document labelling-decision rationale	High
Document retention	■ Establish retention policies for clinical-trial data and safety reports ■ Ensure legal compliance when litigation is anticipated ■ Train employees on document retention requirements ■ Distinguish privileged from non-privileged communications	High
Litigation monitoring	■ Designate personnel to track US and international developments in respect of similar or related products ■ Assess whether Australian products are impugned in overseas litigation and actively monitor developments ■ Monitor trials, rulings on scientific evidence and causation arguments, and settlements in international jurisdictions ■ Engage Australian legal advisers when overseas litigation trends emerge	Medium
Insurance coverage	■ Review insurance policies for coverage scope, exclusions and notification requirements ■ Assess adequacy of insurance limits given settlement and adverse findings trends ■ Ensure timely insurer notification ■ Evaluate additional insurance coverage needs	Medium
Marketing practices	■ Ensure promotional and public facing materials represent safety accurately ■ Develop a communications protocol to ensure consistency in messaging ■ Implement robust review processes ■ Train sales representatives to deliver balanced presentations ■ Review physician engagement programs	Medium
Healthcare professional engagement	■ Maintain communication channels for safety information ■ Provide evidence-based prescribing information ■ Respond promptly to safety enquiries ■ Document interactions with relevant healthcare professionals	Low
Crisis management	■ Establish protocols for litigation threats and adverse publicity ■ Identify key stakeholders for crisis response ■ Prepare media communication strategies ■ Conduct scenario planning exercises	Low

1.2

Patent litigation and preliminary injunctions in Australia

Interlocutory injunctions in Australian patent disputes: why they are becoming harder to obtain

Lead author: Simone Mitchell, Partner and Life Sciences Lead

"In Australia's current patent landscape, the strategic advantage often lies not in assuming an injunction will be available, but in being prepared for the possibility that it will not."

Simone Mitchell

Chapter summary

Interlocutory injunctions have long been an important mechanism for protecting market exclusivity while patent disputes are resolved for life sciences organisations in Australia. Recent Federal Court decisions, however, suggest a more cautious approach, particularly in pharmaceutical patent matters.

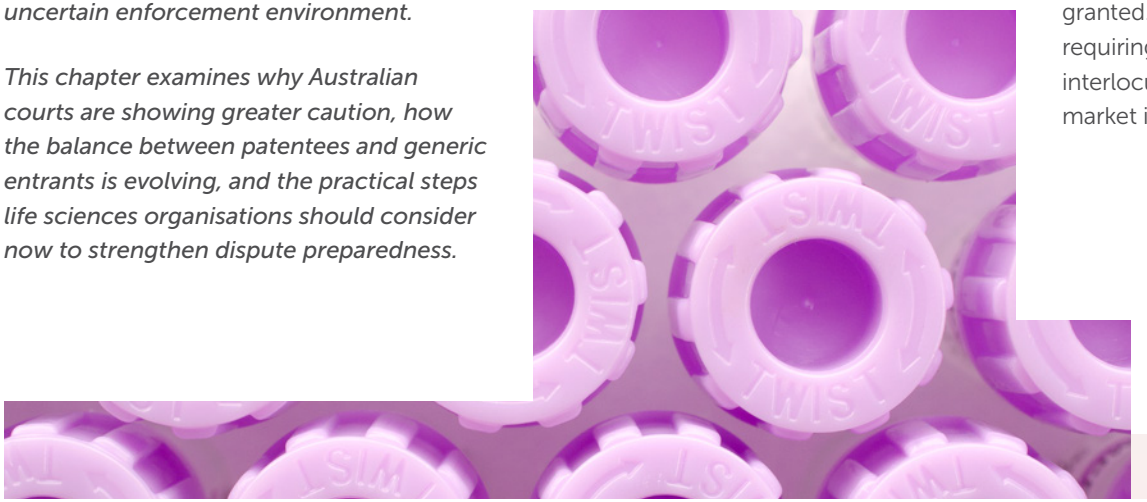
This shift has significant commercial implications. The outcome of an interlocutory injunction application can influence launch timing, pricing, market share, Pharmaceutical Benefits Scheme (PBS) dynamics and the value of a patent portfolio. For innovators and challengers alike, the issue is no longer simply whether an injunction can be obtained, but whether the business is prepared for a more uncertain enforcement environment.

This chapter examines why Australian courts are showing greater caution, how the balance between patentees and generic entrants is evolving, and the practical steps life sciences organisations should consider now to strengthen dispute preparedness.

Introduction

Robust patents are pivotal to the life sciences industry, underpinning investment in research and development, supporting commercialisation and fostering innovation. In an environment where product lifecycles are long, regulatory hurdles are significant, and the cost of bringing new treatments to market is high, decisions about when to enforce – or challenge – patent rights can be critical to commercial success.

Interlocutory injunctions, sometimes referred to as preliminary injunctions, are court orders that temporarily restrain the conduct of alleged infringers pending the outcome of litigation.



Emerging trend: Interlocutory injunctions are becoming harder to obtain

Recent Federal Court decisions suggest a growing judicial caution in granting interlocutory injunctions in life sciences patent disputes, particularly those involving PBS-listed medicines. While each case turns on its particular facts, the combined effect of recent judgments has been to make preliminary relief more difficult to secure than in earlier periods.

Two developments in particular have contributed to this shift. First, courts are applying greater scrutiny to the potential consequences of the 'usual undertaking as to damages', particularly where generic market entrants or the Commonwealth may suffer losses if an injunction is wrongly granted. Secondly, courts are increasingly requiring robust and detailed evidence at the interlocutory stage, especially in relation to market impact and patent validity.

Legal framework

An interlocutory injunction is an extraordinary remedy granted at the discretion of the Court. Its purpose is to preserve the status quo and prevent harm that cannot be adequately compensated by damages before the substantive issues in a dispute are determined at trial. While interlocutory injunctions are not unique to patent litigation, disputes in the life sciences sector – particularly pharmaceutical patent disputes – have been a frequent battleground for such applications.

In patent litigation, the Federal Court of Australia applies a well-established two-limb test when considering whether to grant interlocutory relief.

Prima facie case (serious question to be tried)

The applicant – typically the patentee or its exclusive licensee – must establish that there is a serious question to be tried regarding infringement of the patent. The threshold is relatively low: the applicant does not need to prove its case, but must show that the claim is not frivolous or vexatious and that there is a sufficient likelihood of success to justify preserving the status quo.

A respondent may seek to qualify this element by demonstrating that there is also a serious question to be tried as to the validity of the patent. In practical terms, this means arguing that the injunction should **not** be granted because the patent may ultimately be held invalid, and the competitor would therefore have been wrongly restrained.

Balance of convenience

The Court must weigh the potential harm to each party depending on whether the injunction is granted or refused. Relevant considerations may include the likelihood of a final injunction being granted, potential market disruption, loss of market share, reputational harm, and the public interest – including access to affordable medicines.

The respective strengths of the infringement and validity cases will also influence this assessment.

The Court retains broad discretion and may also consider additional factors, including the conduct of the parties, any delay in bringing the application, and whether the respondent has offered undertakings to limit potentially infringing conduct pending resolution of the dispute.

The undertaking as to damages

A party seeking an interlocutory injunction will generally be required to give the Court the 'usual undertaking as to damages' (as suggested in the Federal Court's Usual Undertaking as to Damages Practice Note (**GPN-UNDR**)).[36] In practical terms, this means the applicant may later be ordered to compensate the respondent or affected third parties if the injunction is ultimately found to have been wrongly granted.

Claims under such undertakings are complex and may only be assessed after the substantive issues in the litigation – including any appeals – have been determined. These assessments often involve extensive expert evidence and analysis of counterfactual scenarios to determine what losses would have occurred had the injunction not been granted.

Key developments influencing the Federal Court's approach

The significance of the undertaking as to damages

From the mid-2000s, it was reasonably common for the Federal Court to grant interlocutory injunctions in pharmaceutical patent disputes. One important reason for this was the weight given by courts to the mandatory price reductions introduced to the PBS in 2005. The listing of the first generic or biosimilar brand on the PBS typically triggers a statutory price reduction that is widely regarded as effectively irreversible.

Historically, this potential price reduction was treated as a form of irreparable harm to the patentee. Courts were therefore prepared, in appropriate circumstances, to grant interlocutory injunctions to prevent a generic entrant from triggering those reductions before the underlying patent dispute had been determined.

However, the Federal Court's decision in Sigma Pharmaceuticals *(Australia) Pty Ltd v Wyeth [2018] FCA 1556 (**Sigma**)*[37] marked a significant turning point in the Court's consideration of interlocutory injunctions in pharmaceutical patent litigation.

In *Sigma*, Wyeth had previously obtained interlocutory injunctions restraining generic competitors from entering the market. After Wyeth's patents were ultimately found to be invalid, several generic manufacturers – together with the Commonwealth of Australia – sought compensation pursuant to the undertaking as to damages Wyeth had provided to the Court when the injunctions were granted. Wyeth was ultimately ordered to pay compensation.

The proceedings that followed were extensive. The judgment alone exceeded 400 pages and followed a 27-day hearing exploring complex counterfactual questions regarding how the pharmaceutical market would have evolved had the interlocutory injunctions not been granted.

Justice Jagot observed[38]**:**
Hindsight makes one thing certain. Knowing what has occurred, it could never have been concluded … that it would be easier for the generics to prove their loss if the interlocutory injunctions were wrongly granted than for Wyeth to prove its loss if the interlocutory injunctions were withheld and the method patent was valid.

The decision highlighted the substantial complexity and potential financial exposure associated with the undertaking as to damages.

> *"The increasing significance of the undertaking as to damages has materially reshaped how courts approach interlocutory injunctions in pharmaceutical patent disputes."*
>
> Simone Mitchell

Following *Sigma*, and in light of the Commonwealth's attempts to recover multimillion-dollar PBS losses as a 'person affected' by the operation of interlocutory injunctions in several pharmaceutical patent cases, the Federal Court's approach to such applications has become noticeably more cautious.

In various subsequent matters, the Court has refused interlocutory relief. While each decision ultimately turns on its own facts, courts have increasingly pointed to the speculative nature and difficulty of quantifying losses suffered by restrained generic entrants – and potentially by the Commonwealth – where injunctions are later found to have been wrongly granted.

Other market dynamics may also influence the balance of convenience. For example, where an innovator organisation is transitioning the market towards a second-generation product, courts may consider whether the market available to a generic entrant would in any event be diminished by the time it is able to launch.

The evolving judicial approach can be seen in the pattern of recent Federal Court decisions summarised on the following page.

PBS price reductions shape the balance of convenience in patent disputes

A distinctive feature of the Australian pharmaceutical market is the PBS, through which the Federal Government subsidises prescription medicines listed on the Schedule of Pharmaceutical Benefits.

Under the PBS framework, the entry of a first generic brand can trigger statutory price reductions and price disclosure mechanisms.

These reductions are widely understood to be practically irreversible.

Prior to the Sigma decision, this factor frequently weighed in favour of granting interlocutory injunctions.

As noted in *Regeneron Pharmaceuticals, Inc v Sandoz Pty Ltd [2025] FCA 1067*, although the Minister technically retains discretion to reverse a PBS price reduction, there is no evidence that such a reversal has occurred once a generic product has launched with supply.

However, following Sigma, the risk of PBS price reductions alone has generally been insufficient to justify the grant of interlocutory relief. Courts have recognised that, despite the complexity of assessing losses associated with PBS price changes, those losses may not necessarily be more difficult to quantify than losses arising from a wrongly granted injunction.

The operation of the PBS therefore continues to play a central role in shaping the commercial dynamics of pharmaceutical patent disputes in Australia.

Decision date	Citation	Outcome
16 February 2026	*AstraZeneca AB v Pharmacor Pty Ltd* [2026] FCA 88	Granted
5 December 2025	*Janssen Pharmaceutica NV v Juno Pharmaceuticals Pty Ltd* [2025] FCA 1538	Granted
3 September 2025	*Regeneron Pharmaceuticals, Inc. v Sandoz Pty Ltd* [2025] FCA 1067	Refused
17 December 2024	*Abbey Laboratories Pty Ltd v Virbac (Australia) Pty Ltd* [2024] FCA 1488*	Refused
16 December 2021	*Biogen International GmbH v Pharmacor Pty Ltd* [2021] FCA 1591	Refused
11 April 2019	*Mylan Health Pty Ltd v Cipla Australia Pty Ltd* [2019] FCA 506	Refused
22 February 2019 19 December 2018	*Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd [2019] FCAFC 28* *Sanofi-Aventis Deutschland GmbH v Alphapharm Pty Ltd* (No 3) [2018] FCA 2060	Appeal dismissed Refused
19 October 2018 *Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth* [2018] FCA 1556		
12 June 2018	F. Hoffman-La Roche AG v Sandoz Pty Ltd [2018] FCA 874	Granted in part
22 December 2017	*Apotex Pty Ltd v Cipla Ltd* [2017] FCA 1627	Granted
18 December 2017	*InterPharma Pty Ltd v Hospira, Inc (No 3)* [2017] FCA 1536	Granted
27 November 2017	*Janssen Sciences Ireland UC v Alphapharm Pty Ltd* [2017] FCA 1399	Granted
19 May 2014 18 March 2014	*Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCAFC 59 *Warner-Lambert Company LLC v Apotex Pty Ltd* [2014] FCA 241	Appeal allowed – PI granted Granted in part
26 November 2013	*Eli Lilly and Company v Generic Health Pty Ltd* [2013] FCA 1254	Granted
28 May 2013	*Reckitt Benckiser Healthcare (UK) Ltd v GlaxoSmithKline Australia Pty Ltd* [2013] FCA 583	Granted
6 March 2013 16 March 2012	*Generic Health Pty Ltd v Otsuka Pharmaceutical Co., Ltd* [2013] FCAFC 17 *Otsuka Pharmaceutical Co Ltd v Generic Health Pty Ltd* [2012] FCA 239	Appeal dismissed – PI upheld Granted
28 September 2012	*Novartis AG v Hospira Pty Limited* [2012] FCA 1055	Granted
31 August 2012	*Merck Sharp & Dohme Corp v Apotex Pty Ltd* [2012] FCA 928	Granted
9 March 2012	*Watson Pharma Pty Ltd v AstraZeneca AB* [2012] FCA 200	Granted
14 December 2011	*Apotex Pty Ltd v AstraZeneca AB* [2011] FCA 1520	Granted
1 February 2011	*Interpharma Pty Ltd v Aventis Pharma SA* [2011] FCA 32	Refused

*Veterinary product

Increasing evidentiary demands

The quality and scope of evidence presented in interlocutory injunction applications has also become increasingly significant.

Because interlocutory hearings take place on an urgent basis, the Court's assessment of the relevant issues typically relies heavily on written evidence from both expert and lay witnesses. Cross-examination is rarely permitted except in exceptional circumstances. As a result, the Court must assess competing positions without the benefit of a full trial process.

This can present particular challenges in patent cases involving complex scientific or technical questions. For example, allegations concerning inventive step or technical validity often depend on competing expert opinions that are difficult to evaluate without the benefit of full cross-examination or concurrent expert evidence at trial.

As observed in *AstraZeneca AB v Pharmacor Pty Ltd [2026] FCA 88*, certain validity challenges – particularly those based on inventive step – may be ill-suited to resolution at the interlocutory stage because the Court cannot adequately interrogate competing expert evidence within the limited procedural framework of an injunction hearing.

Preparing the necessary evidence can therefore impose substantial demands on both parties. Lay witnesses within the business may be required to give evidence regarding the likely commercial impact of a competitor's market entry, while expert witnesses may need to address complex technical or economic issues within compressed timeframes.

At the same time, both the parties and the Court must ensure that interlocutory proceedings do not evolve into a 'mini-trial'. Maintaining that balance requires careful planning and a disciplined evidentiary strategy.

Strategic alternative: Expedited trials

In light of the challenges associated with obtaining interlocutory injunctions, parties in some patent disputes are increasingly considering expedited trials as a practical alternative.

Under the Federal Court's *Central Practice Note: National Court Framework and Case Management (CPN-1)*[39] and *Intellectual Property Practice Note 1 (IP-1)*,[40] the Court has the ability to significantly accelerate proceedings where appropriate. In certain circumstances, disputes may be resolved within a fraction of the usual timeframe, sometimes in a matter of weeks rather than months or years.

An illustration of this approach can be seen in *AGL Energy Limited v Greenpeace Australia Pacific Limited [2021] FCA 625*. Although the case involved copyright and trade mark claims rather than patent infringement, the Court declined to determine an interlocutory injunction application and instead proceeded directly to a final hearing of the dispute.

The matter was resolved in less than one month from the commencement of proceedings – a timeframe comparable to that typically required to hear an interlocutory injunction application.

While such timelines may not be achievable in all patent disputes, the Federal Court has demonstrated a willingness to accommodate the commercial imperatives of the parties where possible. For example, where a generic manufacturer intends to launch following the expiry of a compound patent but seeks to challenge a secondary-use patent, the Court may attempt to list the matter for final hearing in time to allow a determination before the anticipated launch date. The Court has also shown flexibility in accommodating deadlines associated with PBS listing processes, which can add significant commercial pressure to the timing of proceedings.

In this context, expedited trials may offer a practical substitute for interlocutory relief. Rather than focusing on the balance of convenience analysis required for a preliminary injunction, the dispute proceeds directly to a determination on the merits.

Expedition can also deliver procedural and cost efficiencies. By compressing timelines and narrowing the issues in dispute, parties may avoid the duplication of costs that can arise where interlocutory proceedings are followed by a full trial. Importantly, expedited proceedings also avoid the need for a patentee to give the usual undertaking as to damages at an early stage of the dispute, and remove the requirement for an alleged infringer to demonstrate its financial capacity to meet any future damages award.

Another advantage is that either party may seek expedition. Both patentees and alleged infringers may therefore utilise the mechanism where rapid resolution of the dispute aligns with their commercial objectives.

However, expedited proceedings bring their own challenges. Most significantly, parties must be prepared to present substantial evidence at the outset of the proceedings. Evidence that might ordinarily be developed over many months must instead be assembled in advance, often before litigation has formally commenced.

Not all disputes are suitable for expedition. Matters involving extensive discovery, multiple parties, or highly complex factual questions may be difficult to resolve within a compressed timeframe. In such circumstances, a truncated process may risk undermining the quality of the court's determination.

Accordingly, while expedited trials offer an increasingly attractive alternative in certain circumstances, parties must carefully weigh the benefits of speed and efficiency against the practical demands of preparing a case for rapid resolution.

> *"Where interlocutory injunctions are increasingly difficult to obtain, expedited trials may offer a more predictable pathway to resolving patent disputes."*
>
> Simone Mitchell

Interlocutory injunctions can no longer be assumed in Australian patent disputes

The evolving approach to interlocutory injunctions in Australian patent litigation has significant implications for the life sciences sector.

Historically, innovators could reasonably expect that interlocutory relief would be available in appropriate circumstances to prevent generic entry while a patent dispute was resolved. Recent decisions suggest that assumption can no longer be taken for granted. Courts are increasingly attentive to the potential consequences of wrongly granted injunctions – particularly where generic entrants or the Commonwealth may suffer losses associated with delayed market entry or PBS pricing dynamics.

For innovators, this creates greater uncertainty around the ability to preserve market exclusivity during the life of a patent dispute. The commercial consequences can be significant. Early generic entry may affect revenue forecasts, investment decisions and the broader economics underpinning research and development.

At the same time, the shift reflects competing public policy considerations. Access to affordable medicines, the efficient operation of the PBS and the avoidance of unnecessary market disruption are also important elements of a well-functioning life sciences sector. The increasing difficulty in obtaining interlocutory relief has therefore opened the door to alternative approaches, including expedited trials, which may allow disputes to be determined more quickly on their merits.

Against this backdrop, life sciences organisations should consider whether their patent enforcement strategies remain fit for purpose.

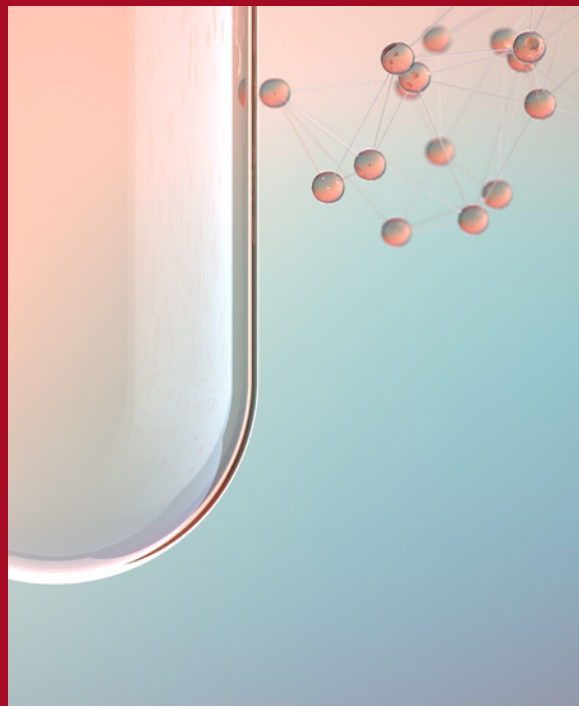
Strategic preparation is therefore likely to become increasingly important. Patent disputes in the life sciences sector frequently involve complex technical questions, extensive expert evidence and detailed economic analysis regarding market impacts. Preparing the evidentiary foundations for an interlocutory injunction application – or for resisting one – may require substantial work well before litigation is formally anticipated.

Organisations may therefore benefit from adopting a more proactive approach to dispute preparedness. This can include identifying potential expert witnesses early, ensuring that key internal data relating to market dynamics is readily accessible, and considering how different litigation pathways – including interlocutory relief, expedited trials or final hearings – may affect commercial strategy.

More broadly, the current landscape also raises questions as to whether the Australian system remains appropriately calibrated when compared with other jurisdictions. For example, the US *Hatch–Waxman legal framework*[41] creates a coordinated system linking regulatory approval and patent litigation, including an automatic stay of generic approval in certain circumstances. While that model is not without criticism, it illustrates how different jurisdictions seek to balance the interests of innovators, generic entrants and public health systems.

In Australia, questions around potential reform – including earlier notification mechanisms for generic entry or other transparency measures – have periodically been raised. Any such reforms would require careful consideration and consultation with industry stakeholders.

However, improving predictability in the timing and resolution of pharmaceutical patent disputes could provide benefits for both innovators and generic manufacturers.



Possible future reforms

In 2020, the Therapeutic Goods Administration (**TGA**)[42] proposed transparency measures[43] that would have required applicants for the first generic version of a medicine to notify the relevant patent holder when their application was accepted for evaluation. The proposal was intended to provide earlier visibility of potential generic entry and allow parties to engage sooner on patent issues.

Under the current framework, patentees typically only become aware of a potential generic threat once the product is entered on the Australian Register of Therapeutic Goods (**ARTG**) – at which point the product may be capable of launching immediately. This compressed timeline can contribute to the urgency surrounding interlocutory injunction applications and expedited proceedings

Although the proposed notification mechanism was not ultimately implemented, the policy discussion illustrates the broader challenge of balancing the interests of innovators, generic entrants and the public health system. Carefully designed transparency mechanisms could provide greater predictability in the timing of pharmaceutical patent disputes while continuing to support competition and access to medicines.

In the meantime, organisations operating in Australia's life sciences sector must navigate a landscape in which interlocutory injunctions remain available but are no longer routinely granted. Strategic planning, robust evidence and a clear understanding of the procedural options available will be essential in managing patent disputes effectively in an environment where such relief cannot be assumed.

Survey results show there is strong appetite from health and life sciences leaders for IP reform, with 81% agreeing reform is needed for timely dispute resolution.

74% support Australia adopting an Orange Book patent linkage equivalent and 70% support PBS reform to restore prices on patent infringement findings.

51% support legislated first mover advantage for generic entrants, indicating genuine industry debate around how to balance innovation incentives with generic / biosimilar market access.

Practical guidance: Interlocutory injunction preparedness checklist

Given the increasingly complex and fast-moving nature of interlocutory injunction proceedings, preparation often needs to begin well before litigation is anticipated. The compressed timeframes for these applications mean that parties must be able to assemble technical, commercial and economic evidence quickly – often within days or weeks.

The following checklist highlights practical considerations for organisations that may seek or resist an interlocutory injunction in Australian patent disputes.

Checklist for preparedness – patentees

1. Identifying the relevant parties

- ☐ Consider whether the ARTG sponsor and/or the PBS Responsible Person (if different from the patentee) should be joined to the proceedings. These entities may be the parties most directly affected by market entry.
- ☐ Review whether an exclusive licence arrangement exists between the patentee and the sponsor and whether that arrangement provides appropriate rights to enforce the patent.
- ☐ Confirm whether existing licence or supply agreements include provisions addressing enforcement of patent rights.

2. Monitoring and early strategic preparation

- ☐ Maintain monitoring of the ARTG and relevant industry sources to identify potential generic entries.
- ☐ Prepare template correspondence addressing potential patent infringement that can be adapted quickly if required.
- ☐ Consider carefully the terms of any pre-litigation undertakings, including arrangements requiring advance notice of launch by a generic entrant.
- ☐ Review the relevant patent portfolio for products approaching potential generic competition and assess likely validity challenges.

3. Preparing technical evidence

- ☐ Identify potential technical experts early. In complex pharmaceutical disputes, multiple experts (for example, formulation chemists and medical specialists) may be required.
- ☐ Ensure that any engagement with potential expert witnesses is conducted through external legal advisers, as communications with experts must be carefully managed.

4. Preparing market and economic evidence

- ☐ Identify internal stakeholders who can provide market evidence, including likely impacts of generic entry on pricing, market share and supply.
- ☐ Ensure relevant commercial data can be accessed and compiled quickly if required for evidence.

5. Understanding the undertaking as to damages

- ☐ Ensure relevant decision-makers within the organisation understand the implications of providing the usual undertaking as to damages, including the potential financial exposure if the injunction is later found to have been wrongly granted.

Checklist for preparedness – defending an interlocutory injunction application

1. Freedom-to-operate analysis

- ☐ Before launching a product in Australia, obtain advice regarding the relevant patent landscape, including potential validity issues and any applicable patent term extensions.

2. Strategic response planning

- ☐ Prepare responses to potential allegations of threatened infringement, including a validity analysis of relevant patents.
- ☐ Consider whether any pre-launch undertakings may be appropriate, such as advance notice of launch.
- ☐ Where relevant patents have been invalidated in other jurisdictions, consider how those decisions may inform the Australian strategy.

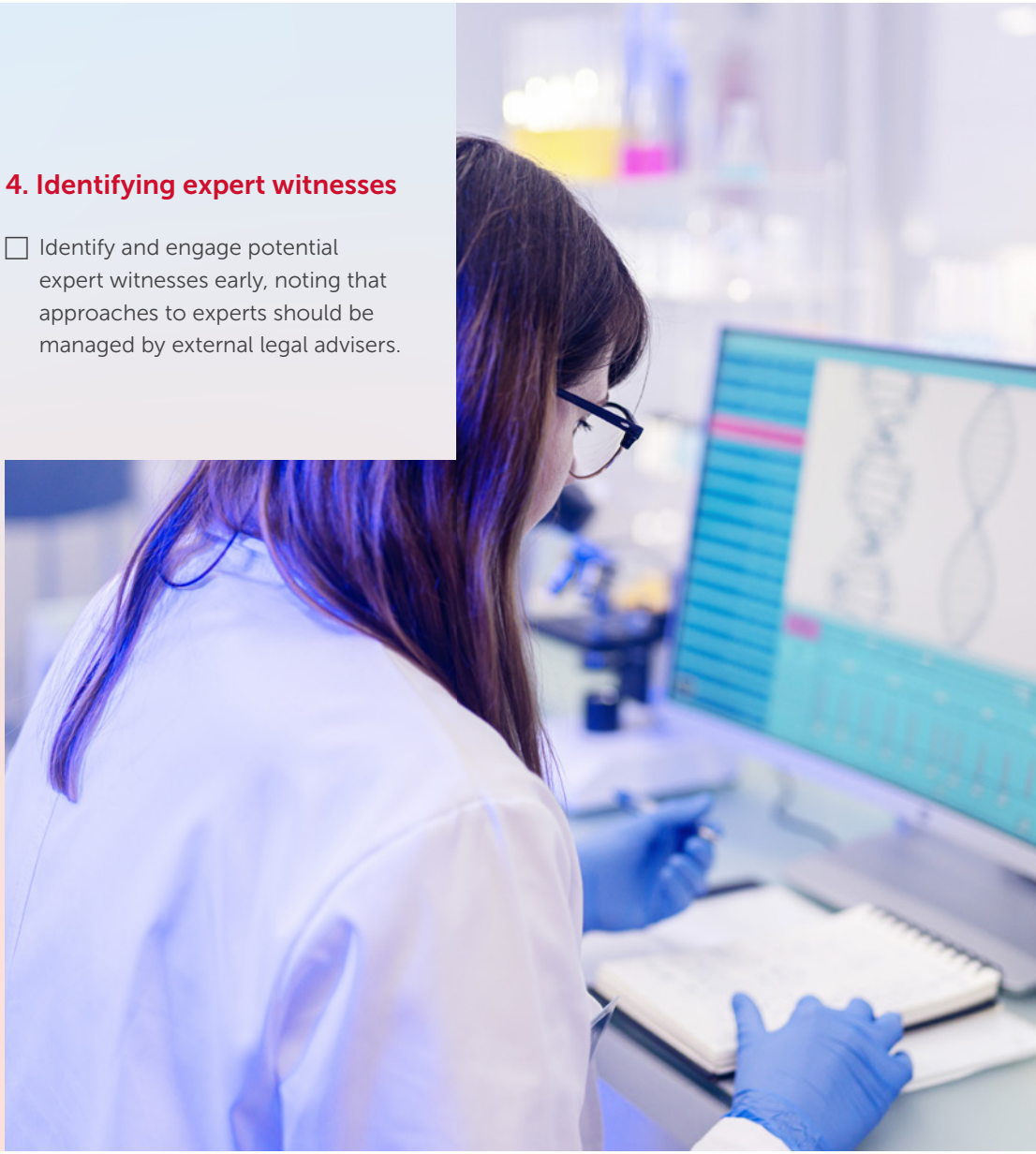
3. Evidence preparation

- ☐ Identify potential validity arguments that may be raised at the interlocutory stage, including prior art or patent term extension issues.
- ☐ For secondary medical use patents, consider whether a skinny-label strategy may reduce infringement risk.
- ☐ Preserve evidence demonstrating readiness to launch, including supply arrangements, manufacturing agreements and product packaging preparation.

Skinny-label strategy involves limiting a product's label to uses not covered by the relevant patent, reducing infringement risk.

4. Identifying expert witnesses

- ☐ Identify and engage potential expert witnesses early, noting that approaches to experts should be managed by external legal advisers.



1.3 An increasingly assertive regulator: TGA enforcement trends

The evolving enforcement approach of the TGA

Lead author:
Jonathan Kelp, Partner

"The TGA is increasingly prepared to pursue significant civil penalties and criminal sanctions where it considers non-compliance to undermine the public protection objectives of the Therapeutic Goods Act."

Jonathan Kelp

Chapter summary

*The regulatory environment for life sciences organisations in Australia is evolving. In recent years, the Therapeutic Goods Administration (**TGA**) has taken a more assertive approach to enforcing compliance with the Therapeutic Goods Act 1989 (Cth) (the **TG Act**), including through civil penalty proceedings, criminal prosecutions and large financial penalties.*

This shift has important implications for sponsors, manufacturers and distributors operating in the Australian market. Regulatory enforcement action can now carry significant financial, operational and reputational consequences.

This chapter examines how the TGA's enforcement posture has evolved, highlights recent regulatory actions and court proceedings, and outlines practical steps life sciences organisations can take to strengthen compliance in an increasingly active regulatory environment.

Introduction

Life sciences organisations operate in a heavily regulated environment. In recent years, the TGA has adopted a more assertive enforcement posture, demonstrating an increasing willingness to take meaningful compliance action, commence court proceedings, and seek substantial civil and criminal penalties.

Historically, the TGA relied primarily on guidance, education and warning letters to address non-compliance, with court proceedings typically viewed as the final enforcement mechanism. However, developments over the past six years indicate a clear shift in regulatory approach, supported by significant Commonwealth funding directed towards strengthening the TGA's compliance and enforcement capability.

Court-based enforcement under the Therapeutic Goods Act

Therapeutic goods for use in humans – including medicines and medical devices – must be registered, listed or included in the Australian Register of Therapeutic Goods (**ARTG**) before they can be lawfully imported into, exported from, manufactured or supplied in Australia, unless an exemption or exclusion applies.

The ARTG is the public record of therapeutic goods that can be legally supplied in Australia and is maintained by the TGA. For sponsors – persons or entities that engage in the import, export, manufacture or supply of therapeutic goods – failure to comply with regulatory obligations can result in significant consequences.

CASE STUDY

Medtronic – record civil penalty for supplying unregistered therapeutic goods

The Medtronic decision illustrates the increasingly significant financial consequences of regulatory non-compliance under the TG Act, even where there is no evidence of deliberate misconduct or patient harm.

In 2024, Medtronic Australasia was ordered to pay a civil penalty of A$22 million for supplying its Infuse Bone Graft Kit while it was not included on the ARTG. This represents the largest penalty imposed in Australia for contraventions of the TG Act.

The conduct in issue arose from a regulatory approval that did not align with commercial practice. The kit had been entered on the ARTG as part of a composite device – the kit together with a metallic spinal fusion cage. When the cage component was withdrawn from supply in August 2018 due to lack of demand, Medtronic continued supplying the kit alone to meet clinical need.

Between 1 September 2015 and 31 January 2020, the kit was supplied 16,267 times across more than 100 hospitals. However, the kit alone was not registered on the ARTG, and its supply in that form contravened the TG Act.

The proceeding was conducted on the basis of agreed facts and admissions. There was no suggestion the contraventions were deliberate, no evidence of patient harm, and Medtronic had no prior non-compliance history.

However, the Court relied on several key factors in imposing the historic penalty:

- each of the 16,267 supplies was treated as a separate contravention rather than a single course of conduct, placing the theoretical maximum penalty in the order of A$162 billion;
- Medtronic received over A$77 million in gross revenue from the unregistered supplies;
- the public protection purpose of the TG Act was materially undermined by the contraventions, even in the absence of proven individual harm; and
- both general and specific deterrence warranted a significant penalty notwithstanding Medtronic's cooperative conduct and absence of prior breach.

LESSON

Regulatory misalignment between product registration and commercial supply can create large-scale liability exposure.

The Court's reasoning on the 'course of conduct' issue – treating each individual supply as a discrete contravention – has significant implications for organisations supplying therapeutic goods at scale.

> *"The Court's reasoning that each individual supply may constitute a separate contravention has significant implications for organisations supplying therapeutic goods at scale."*
>
> Jonathan Kelp

CASE STUDY

Philips – regulatory enforcement following a global medical device recall

The Philips proceeding highlights the TGA's increasing willingness to pursue enforcement action against large-scale medical device suppliers where alleged non-compliance arises in complex post-market and product recall contexts.

In June 2025, the regulator commenced Federal Court proceedings against Philips Electronics Australia Limited. The proceeding concerns the alleged unlawful supply of medical devices containing a polyester-based polyurethane foam used for noise suppression – devices that were the subject of a global recall in 2021.

The TGA alleges that more than 44,000 devices were unlawfully supplied between June 2019 and October 2022 across multiple device types, including devices used by patients with sleep apnoea and those requiring ventilatory support. The regulator further alleges that a replacement silicone foam component introduced for one device model carried its own risk of ventilation failure.

The proceeding will be closely watched by the medical device industry. It involves:

- a major multinational manufacturer;
- a large-scale global recall; and
- complex post-market regulatory obligations.

LESSON

Post-market safety issues and product recalls can quickly escalate into regulatory enforcement proceedings.

The case illustrates how complex safety issues arising during post-market supply can evolve into significant potential regulatory exposure.

The outcome could significantly influence how organisations approach recall management, post-market surveillance obligations and the timing of communications with the TGA.

Insight: The TGA is increasingly willing to pursue significant court-based enforcement

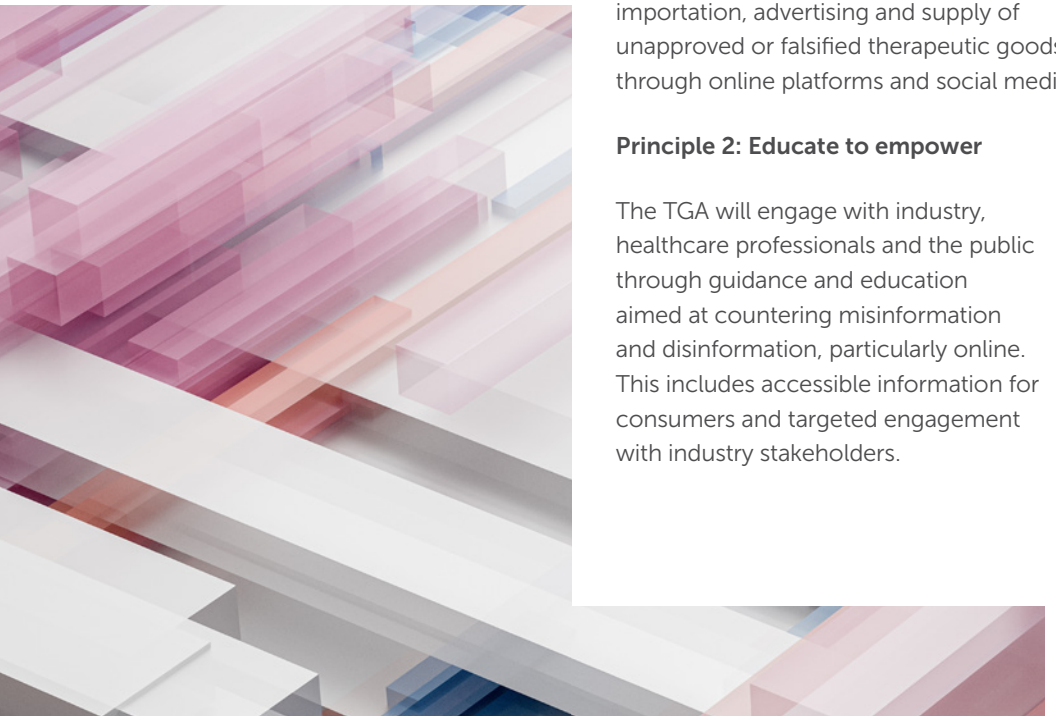
Taken together, the significant penalty imposed on Medtronic and the conduct at the centre of the Philips proceeding reinforce the increasingly assertive enforcement posture being adopted by the TGA.

As the table on the following page illustrates, where alleged contraventions of the TG Act are pursued in court the consequences can be substantial. While the TGA continues to issue infringement notices, particularly for less serious non-compliance, court-based enforcement action – and the scale of penalties imposed – is becoming more prominent.

Organisation	Year	Penalty	Conduct
Peptide Clinics	2019	A$10 million	Advertising unapproved peptide products; ~20,000 contraventions
Oxymed Australia / Director	2021	$2 million (company) A$1 million (director)	Supply and advertising of unregistered hyperbaric oxygen therapy devices
Evolution Supplements / Director	2021	A$11 million (company) A$1 million (director)	Advertising harmful sports nutrition products; 13,000+ contraventions
Enviro Tech Holdings	2022	A$80,000	Importation of face masks in contravention of a COVID-19 exemption
Vapor Kings / Director	2023	A$4.9 million (company) A$100,000 (director)	Unlawful advertising of nicotine vaping products
Medtronic Australasia	2024	A$22 million	Supply of unregistered medical device; 16,267 contraventions
Criminal proceedings			
AusLabs / Smart Labs / iSARMs Director Christopher Ramsay	2023	A$2,225,000 (organisations, aggregate) 2 years' imprisonment and A$300,000 (director)	Manufacture, supply and advertising of unapproved performance enhancing medicines
Elite SARMS Director Ryan McTeigue	2024	2 years' imprisonment (suspended) (director)	Manufacture, supply and advertising of unapproved performance enhancing medicines

The current focus of the regulator

The TGA regularly publishes guidance outlining its approach to compliance and enforcement. Most recently, in January 2026, the regulator released its compliance principles for 2026–2027. These principles continue the TGA's focus on consumer safety, particularly in relation to the online advertising and supply of therapeutic goods through digital platforms, including social media and online marketplaces.



The TGA has identified *five core principles* that guide its compliance and enforcement activities across its regulatory remit, including medical devices, prescription and non-prescription medicines, and other therapeutic goods. These are outlined below.

Principle 1: Safeguarding therapeutic goods

The TGA will continue to prioritise protection of the public from unsafe products. This includes proactive scrutiny of advertising, particularly digital advertising, and enforcement action against the importation, advertising and supply of unapproved or falsified therapeutic goods through online platforms and social media.

Principle 2: Educate to empower

The TGA will engage with industry, healthcare professionals and the public through guidance and education aimed at countering misinformation and disinformation, particularly online. This includes accessible information for consumers and targeted engagement with industry stakeholders.

Principle 3: Protect those most at risk

The regulator will deploy 'diverse and adaptive' strategies to protect vulnerable consumers who may be particularly exposed to harm from therapeutic goods. Risk assessments will consider factors such as the nature of the product, the way it is promoted, the vulnerability of the target audience and the compliance history of the relevant organisation or sector.

Principle 4: Leverage digital capability

The TGA intends to strengthen its digital monitoring capabilities to address emerging technological risks. This includes improved surveillance of online activity and specific attention to risks arising from AI-generated misinformation or misleading endorsements.

Principle 5: Strengthen enforcement

Consistent with recent enforcement activity, the TGA intends to increase public confidence in its regulatory role by taking swift and proportionate action where non-compliance is identified. This includes targeted enforcement against online marketplaces, social media advertising and other digital channels.

These five core compliance principles are supported by *12 priority focus areas*, which are reviewed quarterly and updated as required. As of 1 January 2026, the priority areas include direct-to-consumer in vitro diagnostic (IVD) kits, erectile dysfunction medications, foetal dopplers, listed medicine advertising, medicinal cannabis, melatonin, software as a medical device (SaMD), substandard and falsified therapeutic goods, sunscreen, weight loss medications, therapeutic goods used in cosmetic procedures, and vaping goods.

Notably, the 2023–2025 priority areas relating to unlawful advertising of psilocybin and 3,4-Methylenedioxymethamphetamine (**MDMA**), and medicines and devices promoted as traditional or alternative treatments, no longer feature.

Recent enforcement activity illustrates the TGA's focus on several of these priority areas, including:

(a) **weight loss medications**, with infringement notices issued to businesses for advertising prescription-only weight loss medicines on their websites;

(b) **software as a medical device**, with ongoing monitoring to determine whether the current regulatory framework remains fit for purpose and capable of addressing risks associated with the increasing use of AI-enabled technologies;

(c) **substandard therapeutic goods**, particularly those supplied through online channels, including counterfeit or black-market prescription-only products such as cosmetic injectables and weight loss medicines; and

(d) **sunscreen**, with several product recalls in the second half of 2025 following preliminary testing indicating that SPF levels in certain products may have been lower than stated on labelling.

Practical guidance: Strengthening compliance in an assertive regulatory environment

The evolution in the enforcement landscape gives rise to several important practical considerations for life sciences organisations operating in the Australian market.

Organisations should conduct a risk assessment through the lens of the TGA's priority areas, with particular focus on therapeutic goods and promotional activity involving in vitro diagnostics (IVDs), software as a medical device (SaMD), online advertising, the use of influencers and engagement with healthcare professionals (HCPs).

Advertising and promotional content should be *regularly reviewed across all channels*, including social media, influencers and online marketplaces, having regard to the TGA's proactive scrutiny of digital advertising and its increasing focus on deceptive endorsements and online misinformation.

Organisations should also *treat warning correspondence from the TGA with urgency*. Continued conduct following receipt of a warning – whether formal or informal – has been treated by courts as a significant aggravating factor. A warning from the TGA should not be viewed as an invitation for prolonged negotiation; rather, it is often a signal that enforcement action may follow if the conduct does not cease.

More broadly, governance and escalation procedures should be reviewed to ensure that potential compliance issues can be assessed and remediated quickly. This is particularly important given the TGA's risk-based and graduated enforcement approach, which considers factors such as the risk of harm posed by the conduct, the vulnerability of affected populations, and the size, reach and compliance history of the relevant organisation.

Organisations should also ensure that *internal training and compliance guidance remain current*, reflecting the TGA's continued emphasis on voluntary compliance supported by education and accessible regulatory guidance.

Regulatory approval should be treated as *an ongoing obligation rather than a one-time event*. The Medtronic decision highlights the risks that can arise where regulatory classification and commercial supply practices diverge over time.

Similarly, *post-market surveillance and recall management should be treated as enforcement issues*, not merely operational processes. The Philips proceeding suggests the TGA will closely scrutinise the handling of safety issues, including the timing and adequacy of recalls and the regulatory status of replacement products. Organisations should ensure that safety signals are escalated promptly and that any decision to continue supply pending or following a recall is carefully assessed from a regulatory perspective.

Finally, organisations should ensure that *compliance investment reflects the current enforcement environment*. Significant and ongoing government investment in the TGA's enforcement capability indicates that the regulator's more assertive posture is unlikely to be temporary. Organisations that calibrate their compliance frameworks to an earlier, more permissive regulatory environment may face material risk.

In an environment where the TGA is increasingly prepared to deploy significant enforcement powers, proactive compliance and early escalation of potential issues are likely to be critical in managing regulatory risk.

Policy perspective

Professor The Hon Greg Hunt
Minister for Health 2017-2022

From a policy perspective, why are disputes and regulatory enforcement becoming a more visible feature of the life sciences sector?

The life sciences sector now sits at the centre of some of the most vital trends shaping our future, with rapid advances in genomics, personalised medicine, AI-enabled healthcare/research and surgical robots being used to improve care. This comes at a time when Australia's health system will be facing pressure from ageing populations and increased expectations from Australians as to what healthcare should deliver in safety, efficiency and affordability.

As such, regulatory scrutiny and dispute activity has sought to keep pace with these developments. This should not be read as a sign of hostility to innovation but rather as a signal of maturity to the point that governments, regulators and investors understand the significance of safeguarding the work being done in this vital sector.

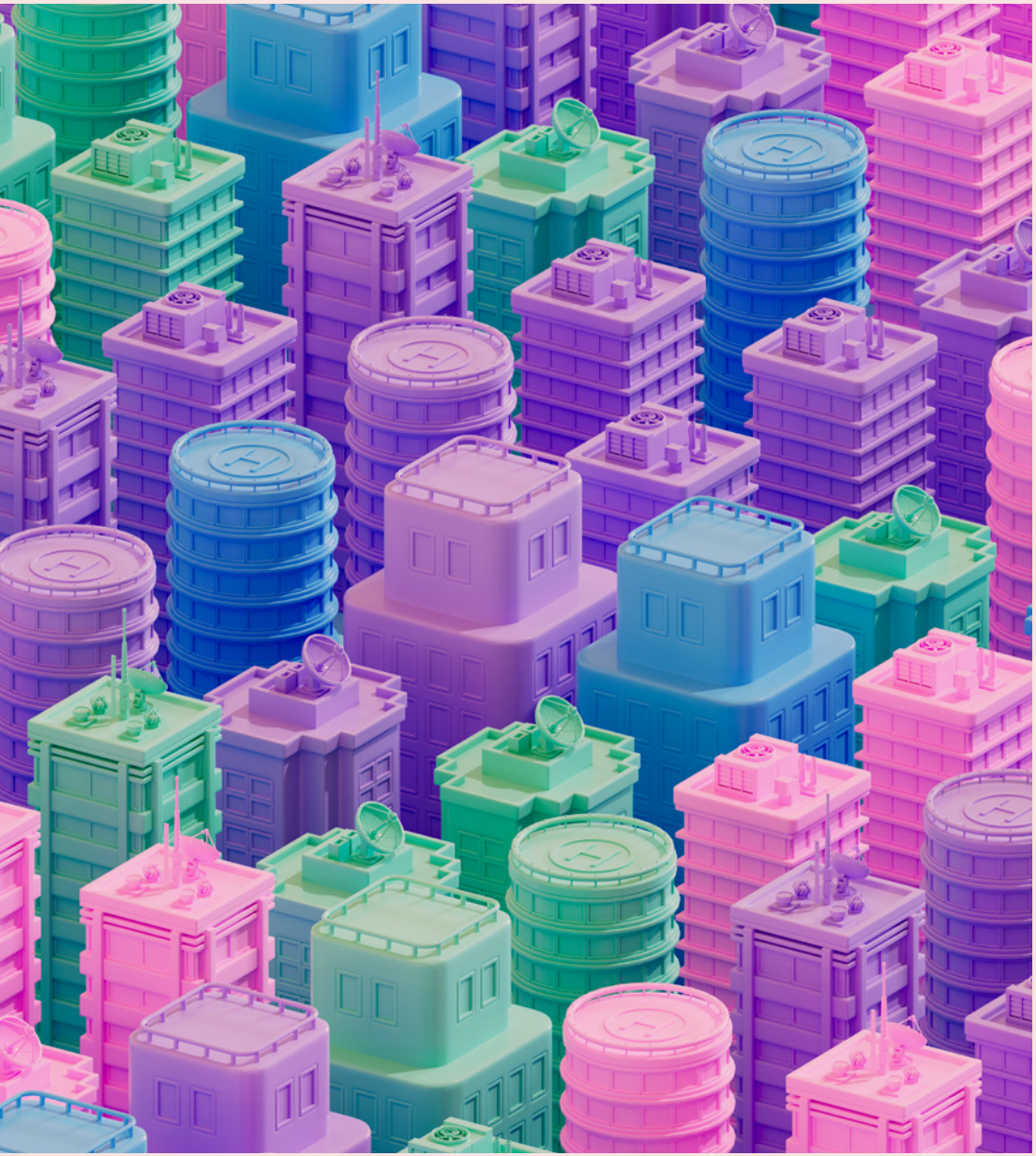
Life sciences products are not ordinary consumer goods. They affect human health, act at points of vulnerability, and rely on clinical evidence, quality, professional conduct and trust. For example, innovations such as AI and algorithm-assisted (or supported) decision making are raising new questions around accuracy, explainability and patient safety. Greater use of health and genomic data is increasing scrutiny around consent and cybersecurity. Faster commercialisation of emerging technologies means regulators must act quickly. And expanded use of telehealth and remote monitoring models is creating new regulatory questions around clinical responsibility and standards of care.

Ultimately, my experience in health policy has reinforced that as the life sciences sector grows in capability and economic significance, the regulatory system must simultaneously protect patients, sustain confidence and enable responsible innovation. From a policy perspective, governments are required to play a much more active role in setting the conditions under which this innovation can be trusted and sustained.

How should life sciences leaders interpret Australia's increasingly active regulatory posture when making investment, innovation or market-entry decisions?

From a policy standpoint, clear regulations should not be interpreted as anti-innovation. If well constructed, a clear regulatory environment can be a hallmark of a durable innovation environment. In practice, whilst unregulated environments allow for short term expansions in technology, reliable investment and market entry decisions will rely on a combination of scientific capability and institutional credibility. Companies are far more likely to succeed when they can operate in an internationally respected framework. This is, for example, why Australia has a disproportionate part of the world's Phase 1 trials.

For leaders making these decisions, the central question is not whether the regulation will matter but how well they understand and engage in it. Recent policy thinking has continued to emphasise research, clinical trial work, genomics, mRNA capabilities and responsible use of digital data. The opportunities in each of these environments come with the expectation that companies will treat regulation as a strategic function and not a downstream compliance exercise.



To create competitive advantage this means engaging with regulatory frameworks, embedding quality systems from the outset with a view to predicting future regulatory standards and recognising that safety and data governance will shape public acceptance. In life sciences, trust can take years to build and only one isolated event to lose, and the consequences are rarely confined to single products or businesses.

What role does trust, particularly around safety, data and technology, play in shaping both regulation and disputes in the life sciences sector?

Trust in this sector is important in three key areas. The first is that of safety. Patients and clinicians must believe that claims about the technologies being used are supported. The second is that of data. Where inadequate, regulatory intervention is likely to follow.

Next, organisations need to show that the increasing amount of data collected for precision medicine, AI and remote monitoring is protected in ways the community considers to be in good faith. If the community loses confidence, regulatory scrutiny and legal risk follows.

The third is the adoption of technology itself – the public will be far more comfortable in supporting innovation when they see a system that can govern it competently and fairly. These pressures will only intensify as digital healthcare and other personalised life sciences technologies become embedded as a staple of daily patient care.

Appropriate and careful scrutiny by lawmakers is not a sign that Australia is becoming closed to innovation. Rather, it is an acknowledgement that innovation in health will continue to carry greater consequence and responsibility.

The most successful organisations will be those that assess this regulation as not an anathema to growth, but as a necessary facet in a sector built on human outcomes. Indeed, precisely because of our hybrid public and private system, Australia has the opportunity to increase our share of discretionary global trials and innovation in health, thereby benefitting both the economy and above all else, patients.

Q&A with Chela Niall

Head of Legal – Walter and Eliza Hall Institute of Medical Research

What is your current role and how long have you been at WEHI?

I am currently the Head of Legal at WEHI (Walter and Eliza Hall Institute of Medical Research). I started at WEHI in 2018, leading a team that was focused on technology transfer and commercialisation, and last year took on responsibility for a consolidated legal function that supports the entire organisation.

How has the role of the in-house legal function evolved in life sciences companies over the past few years?

As in most sectors, legal teams in the life sciences area are expected to evolve and take up new technologies to 'do more with less'. As a not-for-profit in the life sciences/medical research space, this is not a new pressure but it is definitely driving an increased focus on efficiency and particularly what might be achievable with AI and automation. The funding environment is also becoming more fragmented and complex, which creates additional, and very interesting, work for legal teams.

Over my time at WEHI, I have felt a shift in the organisation's approach to legal. When I started, it was viewed as being quite reactive and largely focused on processing high-volume contracts. However, as operations and external engagement have become more sophisticated, the legal team has taken on a more strategic and proactive role.

What is the single most important legal trend that every life sciences company needs to be paying attention to right now and why?

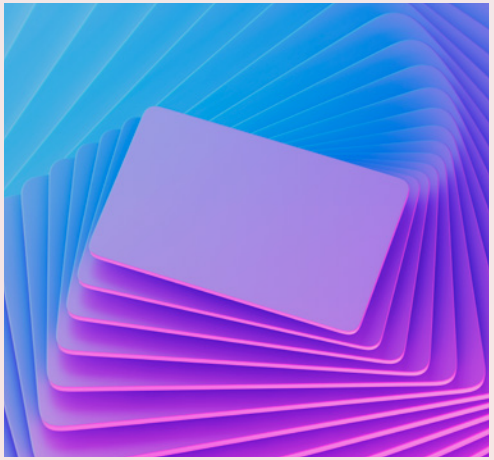
The intersection of AI, data governance and privacy laws. The arrival of AI is changing the way we collect and use data. In the life sciences sector, this includes patient data as well as data that consists of or could lead to valuable IP. Regulators are starting to implement rules and regulations to govern these new interactions which organisations must implement alongside embedding AI in business processes, and be ready to adapt as these laws inevitably evolve.

AI is transforming drug discovery and development – how is your legal team upskilling to advise on the legal risks and opportunities this presents?

We are upskilling in the technology itself to gain a deeper understanding of AI and how WEHI might use it. This enables us to spot emerging issues and advise appropriately. For example, WEHI receives or accesses large numbers of datasets for its research. The providers of those datasets increasingly include AI-related restrictions in data transfer/access agreements – it is important that we advise the business on the need to capture these new categories of restrictions in WEHI's data management processes. These are not new skills, as such: we are learning to apply our existing skills to new subject matter. In parallel, and this goes without saying, we keep up our knowledge of new regulation as it is introduced.

Looking ahead five years, what does the life sciences legal landscape look like?

Provision of legal services will inevitably be AI-enabled, and advising on AI-enabled research will be a greater proportion of our work mix. More routine legal work will be undertaken largely through AI and legal departments will be skewed towards senior lawyers who will undertake the more complex or strategic work that cannot be done by AI. The increasing use of AI will result in a smaller number of junior lawyers being trained and it will therefore become more difficult to recruit lawyers who have the right level of prior experience. This problem won't be unique to those working in life sciences: I think it is a challenge for the entire profession.



Part II – Emerging dispute risks

The life sciences sector is undergoing rapid transformation driven by digital health technologies, AI and expanding global data ecosystems. These developments are creating new legal and regulatory risks that may give rise to future disputes.

The following chapters examine several of the most significant emerging risk areas affecting life sciences organisations in Australia, including privacy governance, AI regulation and insurance exposure.

2.1

Privacy risk in the life sciences sector

Rising enforcement and cyber risk in the handling of sensitive health data.

Lead author: Sonja Read, Partner

"Sensitive health data is no longer just a compliance issue for life sciences organisations – it is a legal, regulatory and cyber risk that demands governance at every level."

Sonja Read

Chapter summary

Privacy and data protection have become critical risk areas for life sciences organisations operating in Australia. Organisations in this sector routinely collect and process large volumes of highly sensitive information, including patient health data, clinical trial information and genetic data. As digital health technologies expand and data-driven research becomes more central to innovation, the regulatory, cyber and litigation risks associated with handling this information are increasing.

Recent developments have materially altered the risk landscape. Regulators are demonstrating a greater willingness to pursue enforcement action following privacy breaches, while cyber incidents affecting healthcare organisations have increased in both frequency and severity. At the same time, reforms to Australia's privacy laws have expanded regulatory powers and introduced new civil penalty pathways.

For life sciences organisations, sensitive health data must now be treated as a strategic risk requiring robust governance, cyber resilience and coordinated oversight across legal, regulatory, IT and commercial functions.

Introduction

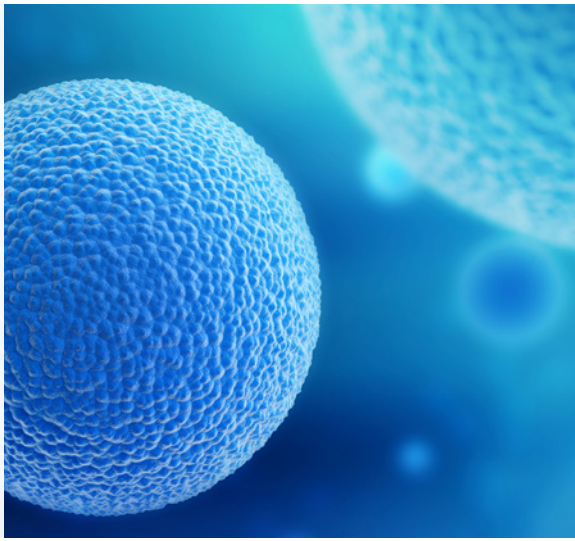
Life sciences organisations in Australia operate under heightened privacy obligations when handling health information. These organisations routinely collect and process highly sensitive data – including patient health records, clinical trial information and genetic data – often across complex networks involving healthcare providers, research institutions and global partners.

The handling of personal information is principally regulated by the *Privacy Act 1988 (Cth)* (the **Privacy Act**) and the Australian Privacy Principles (**APP**s). Recent reforms introduced through the *Privacy and Other Legislation Amendment Act 2024 (Cth)* have strengthened the regulatory framework, including new civil penalty regimes and a statutory tort for serious invasions of privacy. At the same time, regulators are adopting a more proactive enforcement posture, with the Office of the Australian Information Commissioner (**OAIC**) signalling increased scrutiny of how organisations collect, use and safeguard sensitive health information.

Against this backdrop, life sciences organisations must navigate an increasingly complex privacy landscape. This chapter examines the regulatory framework, recent enforcement trends and key compliance challenges, and outlines practical steps organisations can take to strengthen privacy governance.

According to respondents, the leading legal or compliance vulnerabilities over the next three years are:

- Product liability
- Regulatory
- Data, privacy and cyber



Legal framework

Health information is treated as a category of sensitive information under Australian privacy law and therefore attracts heightened protection. The handling of such information is governed primarily by the Privacy Act, which applies to all 'organisations'[44] that provide a 'health service'[45] and hold 'health information'. Unlike many commercial entities that deal primarily with general personal information, life sciences organisations routinely process sensitive health data and therefore operate under stricter privacy obligations.

The Privacy Act establishes 13 APPs, which regulate the collection, use, disclosure and security of personal information.[46] These principles apply to APP entities, including life sciences organisations, and are administered by the Privacy Commissioner within the Office of the Australian Information Commissioner (**OAIC**).

Under the Privacy Act, personal information is broadly defined as information or an opinion about an identified individual, or an individual who is reasonably identifiable.[47] A subset of personal information is classified as sensitive information, which attracts a higher standard of protection.

This category includes health information, genetic information and certain biometric data.[48] Health information itself includes information about an individual's health or medical condition, information collected in providing a health service, and genetic information that may predict the health of the individual or their relatives.[49]

In addition to the Privacy Act, life sciences organisations operating across Australia may also be subject to State and Territory health privacy legislation, particularly in New South Wales, Victoria and the Australian Capital Territory.[50] While these frameworks broadly align with the Privacy Act, organisations conducting multi-site clinical trials, national pharmacy programs or digital health initiatives may need to navigate overlapping regulatory requirements.

Recent and upcoming reforms

The Privacy Act underwent significant reform in late 2024 through the enactment of the *Privacy and Other Legislation Amendment Act 2024 (Cth)* (**POLA Act**), commonly referred to as the 'tranche 1' privacy reforms. These reforms introduced a range of measures aimed at strengthening the protection of individuals' personal information and expanding the enforcement powers available to the Privacy Commissioner.

A number of the reforms commenced on 10 December 2024 when the POLA Act was enacted, with additional changes being progressively implemented through 2025 and 2026.

Several of these reforms are particularly significant for life sciences organisations, as shown in the table on the following page.

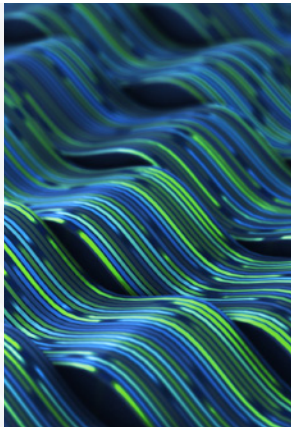
These reforms require organisations not only to update their privacy policies, but also to ensure that their use of automated systems aligns with broader expectations under the Privacy Act regarding transparency and fair handling of personal information.

In addition to these domestic reforms, the Privacy Act also has significant extraterritorial reach, which can affect international life sciences organisations conducting clinical trials or handling health data relating to individuals in Australia.

Surveyed health and life sciences leaders reported clinical trial data and patient medical records are the most frequently handled sensitive data types in their organisations.

90% of these organisations have undertaken a data audit and mapping process to understand data holdings and authorisations in the last three years.

75% of respondents are at least moderately concerned about OAIC scrutiny over the next two to three years.



Key reform	Implications for organisations
Expanded civil penalty regime	The POLA Act introduced a lower-tier civil penalty regime allowing the Privacy Commissioner to issue infringement notices for certain contraventions of the APPs, including failures relating to privacy policy transparency, anonymity options and direct marketing opt-out mechanisms. Breaches may attract penalties of up to 1,000 penalty units (approximately A$330,000) for bodies corporate. The reforms also introduced a mid-tier civil penalty regime for certain interferences with privacy, carrying maximum penalties of 10,000 penalty units (approximately A$3.3 million), and expanded the Commissioner's enforcement toolkit through the introduction of compliance notices requiring organisations to remedy contraventions of the Privacy Act.
Clarification of security and retention obligations	The POLA Act also strengthened the operation of APP 11, which requires organisations to take reasonable steps to protect personal information from misuse, interference and loss, and from unauthorised access, modification or disclosure. The introduction of APP 11.3 clarifies that 'reasonable steps' include both technical and organisational measures designed to safeguard personal information. This clarification is particularly relevant for life sciences organisations that routinely hold large volumes of sensitive health data and are increasingly exposed to cyber threats.
Cross-border disclosure mechanisms	The reforms also introduced a mechanism allowing the Government to prescribe countries and binding schemes that provide privacy protections substantially similar to the APPs. This mechanism is intended to assist organisations when assessing whether personal information can be disclosed to overseas recipients in accordance with APP 8. The list of prescribed countries has not yet been finalised. However, the mechanism is likely to be particularly relevant for life sciences organisations engaged in: ■ international clinical trials; ■ global pharmacovigilance programs; and ■ cloud-based digital health platforms involving offshore data processing.
Statutory tort for serious invasions of privacy	A new statutory tort for serious invasions of privacy commenced on 10 June 2025. The tort provides individuals (but not corporations) with the ability to bring civil proceedings where their privacy has been seriously invaded, either through: ■ intrusion upon seclusion; or ■ misuse of private information. To succeed, a plaintiff must demonstrate (among other elements) that: ■ they had a reasonable expectation of privacy; ■ the invasion was intentional or reckless; and ■ the invasion was sufficiently serious that the public interest in protecting privacy outweighs competing public interests such as freedom of expression. Given the highly sensitive nature of health information, serious health data breaches may be particularly likely to satisfy the seriousness threshold under this tort.
Automated decision-making transparency requirements	Further reforms relating to automated decision-making (**ADM**) will commence on **10 December 2026**. These amendments introduce **APP 1.7** to **1.9**, requiring organisations to disclose in their privacy policies where automated systems are used to make, or substantially assist in making, decisions that could significantly affect an individual's rights or interests. Where such systems rely on personal information, organisations must disclose: ■ the types of personal information used; and ■ the types of decisions made or facilitated by the automated system. In the life sciences context, automated decision-making may arise in areas such as patient eligibility assessments, clinical trial screening, pharmacovigilance and digital therapeutics.

Extraterritorial application of the Privacy Act

What constitutes an 'Australian link'?

International clinical trial sponsors and multinational life sciences organisations should be aware that the Privacy Act can apply extraterritorially to organisations with an 'Australian link' under section 5B. This means the Privacy Act may apply regardless of where an organisation is headquartered, incorporated or makes operational decisions.

An Australian link arises automatically where the entity is:

- incorporated in Australia;
- a partnership formed in Australia;
- a trust created in Australia; or
- an unincorporated association with central management and control in Australia.

Importantly, foreign entities that carry on business in Australia may also have an Australian link even where they do not maintain a physical presence in the country. The concept of 'carrying on business' is not expressly defined in the Privacy Act. Case law indicates that the test focuses on whether an organisation undertakes activities in Australia on a systematic or repetitive basis as part of its business operations.[51]

Activities likely to establish an Australian link

Judicial authority indicates that determining whether business is carried on 'in Australia' generally requires *some physical activity within Australia through human instrumentalities*, although the activity does not need to constitute the bulk of the organisation's business.[52] An organisation does not need to maintain an office in Australia for the test to be satisfied.[53]

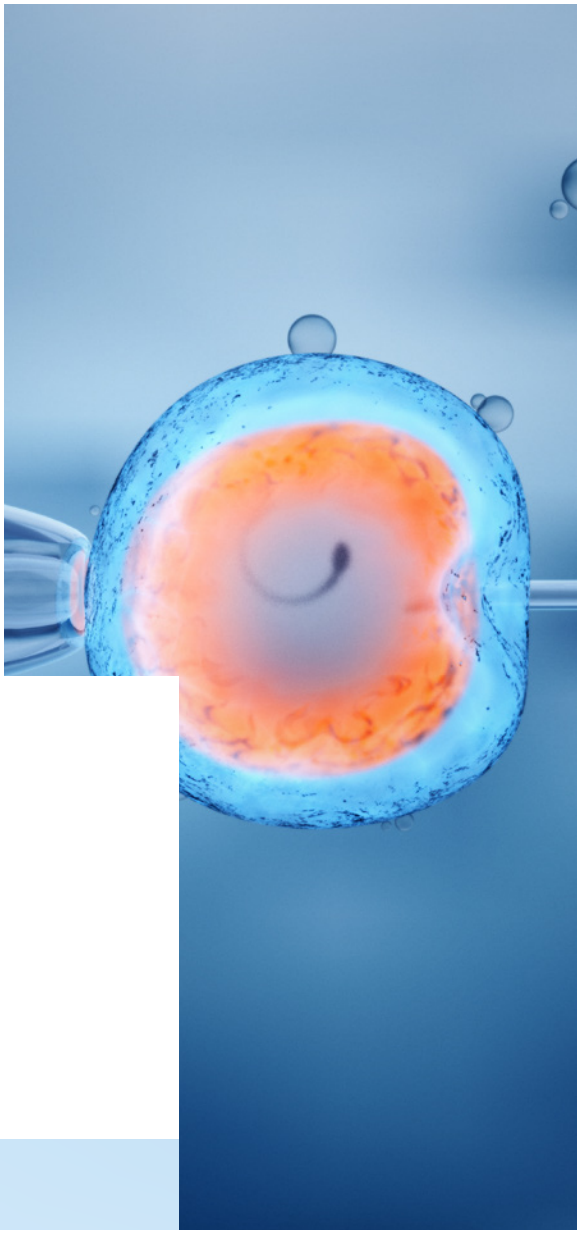
OAIC guidance indicates that an organisation may be considered to carry on business in Australia where it conducts commercial activities in Australia through employees, agents or digital platforms, or where Australian customers or participants form part of its business operations.[54]

Relevance for life sciences organisations

In the life sciences sector, a wide range of activities may establish an Australian link, including:

- establishing or contracting with Australian clinical trial sites;
- engaging Australian contract research organisations (**CROs**);
- recruiting Australian trial participants;
- collecting health information from Australian patients or trial participants (even if the data is processed offshore);
- maintaining ongoing commercial relationships with Australian healthcare providers or research institutions;
- making payments to Australian investigators or research sites; or
- using Australian participant data in global regulatory submissions.

As a result, multinational life sciences organisations involved in clinical trials, pharmacovigilance programs or global research collaborations may become subject to the Privacy Act even where their principal operations are located overseas.



Increased regulatory action

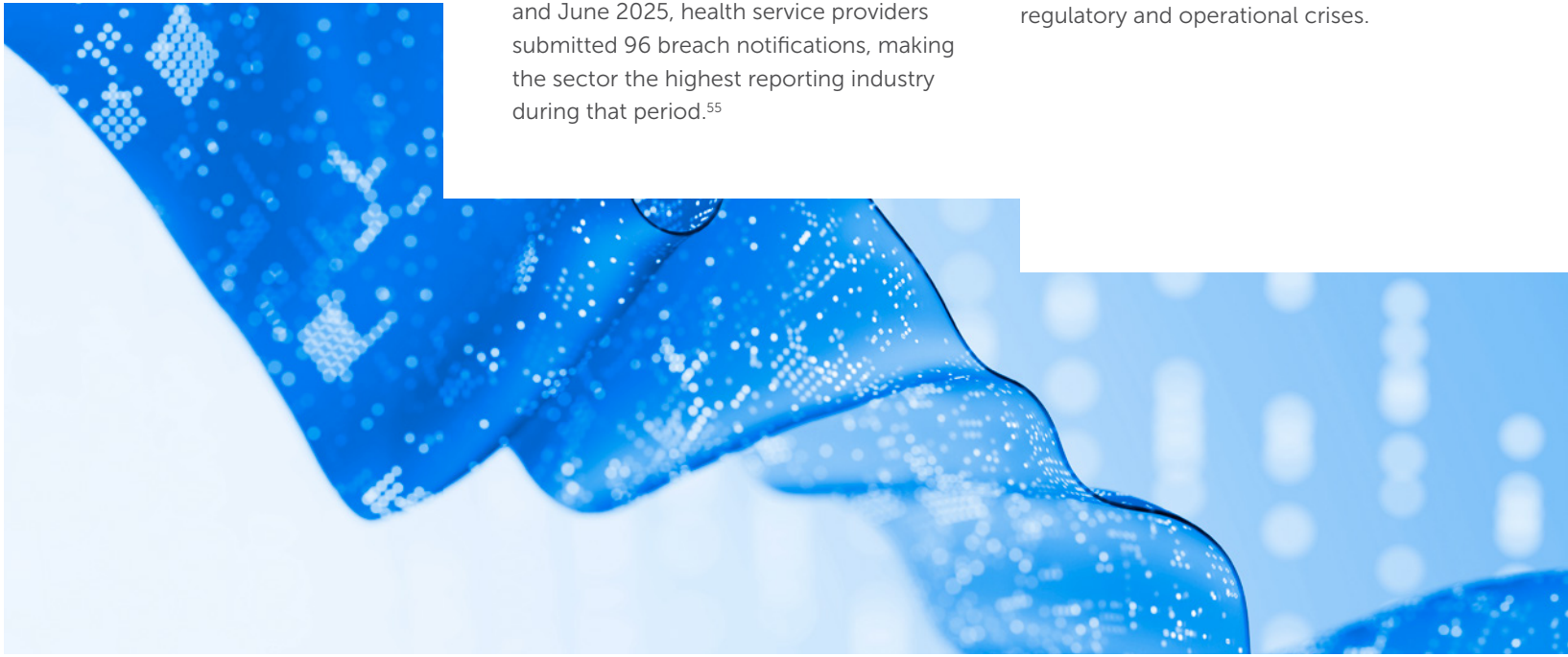
OAIC regulatory action in the health sector

The OAIC has recently signalled a more proactive and enforcement-led approach to privacy regulation. In January 2026, the OAIC commenced its first targeted compliance sweep of privacy policies, reviewing approximately 60 businesses across six sectors for compliance with the Privacy Act – particularly the requirements of APP 1 relating to privacy policies.

Chemists and pharmacists were identified as priority sectors due to the volume and sensitivity of personal information collected in the course of medication provision, including health conditions, prescription histories and patient identifiers.

Recent amendments to the Privacy Act have significantly expanded the regulatory consequences for privacy infringements. Entities with non-compliant privacy policies may now face compliance notices, infringement notices and civil penalties, including penalties of up to A$66,000 for certain contraventions. Importantly, the OAIC's enforcement powers enable it to take administrative action quickly, signalling a shift towards more active regulatory oversight.

As a practical matter, organisations should proactively audit privacy policies against APP 1.3 and 1.4. Clinical laboratories, digital health platforms, sponsors, contract research organisations and other life sciences organisations should treat privacy policy compliance as a core governance priority. Organisations should proactively audit privacy policies against APP 1.3 and 1.4, ensure collection notices accurately reflect current data handling practices, and maintain documentation demonstrating compliance efforts in the event of regulatory inquiry.



Emerging dispute trends in privacy and health information

The Notifiable Data Breaches (**NDB**) scheme, introduced through the *Privacy Amendment (Notifiable Data Breaches) Act 2017 (Cth)* and in operation since February 2018, requires organisations regulated by the Privacy Act to notify both the OAIC and affected individuals where an eligible data breach is likely to result in serious harm.

The OAIC publishes regular statistics on reported data breaches, that consistently identify the health sector as one of the most affected industries. Between January and June 2025, health service providers submitted 96 breach notifications, making the sector the highest reporting industry during that period.[55]

The health sector's persistent vulnerability reflects several structural factors, including:

- the large volumes of sensitive data held across healthcare systems;
- complex data-sharing arrangements between providers, laboratories, pharmacies, insurers and researchers;
- reliance on legacy IT infrastructure in parts of the sector; and
- the high value of medical and personal data to cybercriminals.

Recent cyber incidents illustrate how privacy failures can escalate into major regulatory and operational crises.

Major health sector breaches

Major cyber incidents in the Australian healthcare sector illustrate the scale of legal, regulatory and operational consequences that can arise when sensitive health data is compromised.

CASE STUDY

The Medibank breach – regulatory and prudential consequences of cyber failure

In October 2022, attackers accessed Medibank's systems and exfiltrated data relating to approximately 9.7 million customers. Rather than encrypting systems, the attackers threatened to publish the stolen data unless a ransom was paid. Medibank refused, resulting in the release of personal and health information on the dark web.

The OAIC subsequently commenced civil penalty proceedings in the Federal Court, alleging that Medibank failed to take reasonable steps to protect personal information under APP 11 of the Privacy Act.

The breach also triggered prudential consequences. The Australian Prudential Regulation Authority required Medibank to increase its capital adequacy by A$250 million until cybersecurity deficiencies were remediated.

LESSON

Cyber breaches involving health data can trigger multiple regulatory consequences

The Medibank breach demonstrates that privacy incidents involving health data can trigger multiple regulatory responses simultaneously, including privacy enforcement, prudential supervision and reputational damage. For life sciences organisations, cyber resilience is therefore not simply an IT issue but a core governance and regulatory risk.

CASE STUDY

Australian Clinical Labs – enforcement risk for breach management failures

In February 2022, a cyber incident involving Australian Clinical Labs resulted in the compromise of highly sensitive patient data held by Medlab Pathology, including pathology results, Medicare numbers and credit card information. Approximately 86GB of data was later published on the dark web.

Following investigation, the Federal Court declared that the organisation had contravened several provisions of the Privacy Act, including failing to take reasonable steps to protect personal information and failing to conduct a timely assessment of the breach under the Notifiable Data Breaches scheme.

In October 2025 the Federal Court imposed civil penalties of A$5.8 million for contravening multiple provisions of the Privacy Act, including sections 13G(a), 26WH(2) and 26WK(2).

LESSON

Breach response failures can lead to significant regulatory penalties

The decision highlights the OAIC's increasing willingness to pursue civil penalty litigation where organisations fail not only to secure personal information but also to comply with breach assessment and notification obligations.

CASE STUDY

MediSecure – operational consequences of data retention risk

In April 2024, MediSecure experienced a cyber incident involving historical prescription records and health information accumulated over many years. The incident highlighted risks associated with data retention practices, legacy system security and the storage of sensitive information beyond operational necessity.

The financial and operational consequences were severe. MediSecure was unable to absorb the costs associated with incident response and regulatory compliance and ultimately entered voluntary administration.

The OAIC closed its inquiries without investigation due to the company's insolvency.

LESSON

Long-term retention of health data can create existential operational risk

The incident illustrates that privacy failures can create existential business risks, particularly where organisations retain large volumes of historical health data without strong governance or cybersecurity protections.

Challenges for life sciences organisations

Life sciences organisations operating nationally may also need to navigate overlapping regulatory regimes beyond the Privacy Act. In addition to State and Territory health privacy legislation in New South Wales, Victoria and the Australian Capital Territory,[56] some organisations may also be affected by the *My Health Records Act 2012 (Cth)*, the *Healthcare Identifiers Act 2010 (Cth)*, the *National Health (Privacy) Rules 2025* and, in some cases, the *Security of Critical Infrastructure Act 2018 (Cth)*.

These overlapping frameworks are particularly relevant for organisations conducting multi-site clinical trials, digital health initiatives, real-world evidence programs or operating healthcare platforms at scale.

De-identification as an ongoing governance obligation

Under the Privacy Act, whether data is anonymous or de-identified is context dependent. Information that appears de-identified in one setting may become identifiable when combined with other datasets or accessed by parties with different capabilities.[57]

For life sciences organisations using de-identified datasets for research, product development, real-world evidence generation or AI training, the key question is whether re-identification risk remains low in practice. This requires ongoing assessment of technical safeguards, contractual protections and the capabilities of those who may access or link the data.

Life sciences organisations should therefore treat de-identification as an ongoing governance obligation rather than a one-time technical exercise.

CASE STUDY

I-MED Radiology Network – governance of de-identified health data

The I-MED Radiology Network (I-MED) matter illustrates the increasing regulatory scrutiny surrounding the use of de-identified health data in AI development.

In July 2025, the Office of the Australian Information Commissioner (**OAIC**) concluded preliminary inquiries into the handling of patient imaging data by I-MED, Australia's largest diagnostic imaging provider.

Between 2020 and 2022, I-MED shared fewer than 30 million patient studies, including X-rays, CT scans and associated diagnostic reports, with Annalise.ai – a former joint venture with Harrison.ai – for the purpose of developing and training an AI diagnostic model.

Patients were not notified of this use of their data and did not provide consent. Following media reports in September 2024, the OAIC commenced preliminary inquiries to assess whether the disclosure contravened the APPs, particularly APP 6, which regulates the use and disclosure of sensitive information for secondary purposes.

After reviewing the evidence, the Privacy Commissioner concluded that the data had been de-identified to a sufficient degree that it no longer constituted personal information under the Privacy Act.

The Commissioner noted that I-MED's de-identification practices reflected many of the practices endorsed by the National Institute of Standards and Technology, including:

- cryptographic hashing;
- time-shifting of dates;
- aggregation of outlier data; and
- redaction of embedded identifying text.

The OAIC also recognised the presence of contractual safeguards between I-MED and Annalise.ai, including provisions that:

- prohibited attempts to re-identify individuals;
- required secure storage of the dataset; and
- required notification if personal information was inadvertently disclosed.

While the Commissioner characterised the matter as a useful example of de-identification practices, she emphasised that the findings should not be interpreted as a broader endorsement of I-MED's overall compliance with the Privacy Act.

Insight: De-identified health data remains subject to regulatory scrutiny

The case highlights the importance of robust de-identification governance frameworks when life sciences organisations seek to use health data for research, analytics or AI development.

In particular, the OAIC's analysis emphasised several factors that contributed to the conclusion that the dataset was sufficiently de-identified:

- removal of direct identifiers such as names, addresses and patient ID numbers;
- application of recognised technical de-identification techniques;
- an assessment of the practical likelihood of re-identification occurring;
- contractual safeguards preventing re-identification; and
- ongoing governance and oversight of the data environment.

Together, these measures demonstrate that effective de-identification requires a layered governance approach, combining technical controls, contractual protections and ongoing risk assessment.

Importantly, despite the OAIC's findings, the case generated significant public discussion regarding the secondary use of health data. In response, I-MED subsequently introduced a consent-based approach, seeking patient consent before using de-identified imaging data for AI model training.

The episode highlights that maintaining public trust and transparency may require measures that extend beyond strict legal compliance.

> *"As health data becomes central to AI development, privacy governance can no longer be treated as a compliance exercise – it is a core component of responsible innovation in the life sciences sector."*
>
> Sonja Read

Overseas disclosures and data sovereignty

Cross-border data flows are a defining feature of the life sciences sector. Global clinical trials, international pharmacovigilance databases, multinational research collaborations and cloud-based digital health platforms frequently involve the transfer of personal information outside Australia.

However, these activities can trigger obligations under APP 8, often in circumstances where organisations may not initially recognise that offshore data processing constitutes a disclosure under the Privacy Act.

Under APP 8, where an organisation discloses personal information to an overseas recipient, it must take reasonable steps to ensure that the recipient does not breach the APPs (other than APP 1) in relation to that information.

Importantly, section 16C of the Privacy Act provides that the Australian organisation may be liable for acts or practices of the overseas recipient that would constitute a breach of the APPs.

This accountability model creates particular challenges for life sciences organisations operating in global research and regulatory ecosystems.

Practical scenarios in the life sciences sector

Cross-border disclosures commonly arise in contexts such as:

- global clinical trials involving international research sites;
- pharmacovigilance reporting to global safety databases;
- multinational regulatory submissions requiring pooled datasets;
- cloud-based digital health platforms and medical devices with offshore processing; and
- collaborations with international research institutions or analytics providers.

In these circumstances, the Australian organisation remains responsible for ensuring that overseas recipients handle personal information consistently with Australian privacy law.

Satisfying the 'reasonable steps' requirement

In practice, organisations typically demonstrate compliance with APP 8 by implementing contractual and governance safeguards. These may include:

- binding contractual obligations requiring the overseas recipient to comply with the APPs;
- data transfer agreements within corporate groups;
- due diligence assessing the privacy practices and security standards of overseas recipients; and
- monitoring and audit rights to verify compliance with contractual obligations.

These measures are particularly important in the life sciences sector, where data may move through multiple intermediaries including contract research organisations, data analytics providers and cloud service providers.

Emerging reforms: the 'white list' mechanism

Recent reforms introduced through the Privacy and Other Legislation Amendment Act 2024 (Cth) create a mechanism allowing the Australian Government to prescribe countries or binding schemes that provide privacy protections substantially similar to the APPs.

Where personal information is disclosed to a recipient located in a prescribed jurisdiction, the Australian organisation may not be required to implement additional contractual protections.

However, the list of prescribed jurisdictions has not yet been finalised, meaning organisations must continue to rely on contractual safeguards and due diligence when transferring personal information overseas.

Life sciences organisations should therefore closely monitor the development of the proposed 'white list' framework, as it may materially affect the governance of international research collaborations and cross-border data flows.

Consent and collection complexities in health contexts

Health information is classified as sensitive information under the Privacy Act and is therefore subject to stricter requirements than other categories of personal information. Under APP 3, organisations must generally obtain consent before collecting such information.

Sensitive information may usually only be used for the primary purpose of collection unless an exception applies, such as where the individual has consented, the secondary use is reasonably expected and directly related to the primary purpose, or the activity falls within a permitted health situation under the Privacy Act.

Section 16B of the Privacy Act allows certain research uses of health information without consent where strict conditions are satisfied, including that the research is relevant to public health or public safety, the purpose cannot reasonably be achieved using de-identified data and obtaining consent is impracticable.[58]

For life sciences organisations conducting clinical research, pharmacovigilance or real-world evidence programs, the design of consent frameworks and collection notices is therefore critical to ensuring that secondary uses of health data remain lawful and aligned with patient expectations.

Technical and organisational measures

APP 11 requires organisations to take reasonable steps to protect personal information from misuse, interference and loss, as well as from unauthorised access, modification or disclosure. It also requires organisations to destroy or de-identify personal information once it is no longer needed for a permitted purpose under the Privacy Act.

For life sciences organisations, these obligations can present particular challenges. Health information is inherently sensitive, datasets are often large, and many organisations operate complex digital environments involving clinical research platforms, connected medical devices and cloud-based infrastructure.

Unlike some jurisdictions, Australian privacy law does not prescribe specific cybersecurity standards. Instead, compliance with APP 11 is assessed against a risk-based 'reasonable steps' standard.

Recent reforms introduced by the *Privacy and Other Legislation Amendment Act 2024 (Cth)* clarify that reasonable steps include both technical measures and organisational measures designed to safeguard personal information.

In determining what constitutes reasonable steps, regulators generally consider factors such as:

- the sensitivity of the information, noting that health data attracts particularly high protection expectations;
- the volume of data held, which may increase the potential impact of a breach;
- the likelihood and severity of threats, including ransomware attacks, insider threats and targeted cyber intrusions; and
- the cost and practicality of security measures, although cost alone will rarely justify the absence of widely adopted safeguards.

In practice, life sciences organisations are typically expected to implement a combination of technical and governance controls to protect sensitive health information. These commonly include encryption of sensitive data, strong access controls and authentication mechanisms, active monitoring of systems for security incidents, and organisational measures such as staff training, vendor risk management and tested incident response procedures.

Taken together, these measures form the foundation of a privacy and cybersecurity program capable of meeting the 'reasonable steps' standard under APP 11.

Practical guidance: Privacy governance best practice framework

Life sciences organisations should adopt structured governance measures to ensure that the collection, use and protection of sensitive health information complies with the Privacy Act and the APPs.

The framework on the following pages summarises key governance measures that organisations should consider when managing privacy and cybersecurity risks.

Recent reforms, rising enforcement activity and increasing cyber risk all point in the same direction: privacy governance is becoming a core operational issue for organisations handling sensitive health data. For life sciences organisations, privacy risk can no longer be managed solely through compliance processes. It requires coordinated oversight across legal, regulatory, technology and commercial teams, together with robust governance over how health data is collected, used and protected.

As regulators increase enforcement activity and cyber threats continue to escalate, privacy governance is becoming a central operational issue for organisations handling sensitive health data. For life sciences organisations in particular, effective privacy governance requires coordinated oversight across legal, regulatory, technology and commercial teams, together with clear accountability for how health data is collected, used and protected.

Key requirement	Focus areas	Recommended actions
Governance and accountability Establish clear governance structures with leadership oversight and defined responsibilities for data privacy and cybersecurity.	■ Establishment of a dedicated privacy function with senior management reporting ■ Development of a Privacy Management Plan documenting APP implementation ■ Creation of privacy and security policies covering data collection, use, disclosure, storage and individual rights ■ Board-level privacy and cybersecurity reporting ■ Integration of privacy and cyber risk into enterprise risk management ■ Executive accountability with appropriate resourcing.	■ **Policies:** Develop privacy and information security policies reflecting Privacy Act requirements, including 2025/2026 reforms ■ **Privacy management plan:** Implement a plan outlining APP compliance, breach handling and third-party risk management ■ **Leadership oversight:** Assign executive accountability (e.g. Privacy Officer) with board reporting ■ **Risk management:** Integrate cyber and privacy risk into enterprise risk management.
Data mapping and classification Organisations must know what personal data they hold, where it flows, and how it's handled.	■ Comprehensive inventory of all personal information holdings, including health records, employee data, and customer information ■ Classification of data by sensitivity level (health and other sensitive information, biometric data, genetic information) ■ Mapping of data flows across systems, third parties and international transfers ■ Documentation of lawful bases for collection and processing under the Privacy Act ■ Identification of legacy systems or shadow IT containing unmanaged personal information ■ Data retention periods aligned with legal requirements ■ Regular audits to maintain current data mapping.	■ **Inventory:** Document all personal information held, including sources, storage locations and recipients ■ **Data flow mapping:** Map data flows including cross-border transfers to ensure APP 8 compliance ■ **Classification:** Classify data by sensitivity, with health information requiring strictest controls ■ **Minimisation:** Establish retention schedules and secure deletion processes.
Privacy compliance and data lifecycle management Ensure APP compliance and State/Territory health legislation requirements throughout the data lifecycle.	■ Implementation of consent management systems for optional data uses (marketing, research, AI training) ■ Express consent mechanisms for collecting sensitive health information ■ Processes for communicating material privacy practice changes ■ Controls ensuring data use and disclosure aligns with consent or lawful basis ■ Safeguards for overseas transfers including adequacy assessments ■ PIA processes for new projects, systems or AI applications. ■ Data quality processes to maintain accuracy.	■ **Consent and collection practices:** Review collection and consent mechanisms; maintain records and enable withdrawal ■ **Use, disclosure and cross-border transfer:** Implement controls aligning with consent or lawful basis (APP 6); use safeguards for overseas transfers (APP 8) ■ **PIAs:** Conduct PIAs for new projects involving personal information, especially health data or AI ■ **Data quality:** Maintain accuracy and integrity processes (APP 10); regularly audit and cleanse data ■ **Retention and erasure:** Implement retention policies; securely destroy or de-identify data when no longer needed (APP 11).

Key requirement	Focus areas	Recommended actions
Information security controls and cyber defences Align cybersecurity controls with recognised frameworks and Australian healthcare standards.	▪ Implementation of the Australian Signals Directorate Essential Eight[59] mitigation strategies as baseline protection ▪ Adoption of healthcare-specific frameworks (ISO 27001, NIST Cybersecurity Framework) ▪ Regular vulnerability assessments and penetration testing ▪ Incident detection and response capabilities with 24/7 monitoring for critical assets ▪ Access controls and privileged access management for health data systems ▪ Encryption at rest and in transit ▪ Business continuity and disaster recovery planning ▪ Security controls for medical devices and IoT technologies ▪ Secure software development lifecycle.	▪ **Access control:** Enforce least privilege access with multi-factor authentication ▪ **Encryption:** Use encryption for data in transit and at rest ▪ **Device security:** Ensure cybersecurity in product design; regularly patch systems including medical devices ▪ **Monitoring:** Implement continuous network monitoring with intrusion detection ▪ **Secure development:** Integrate cybersecurity into development; perform regular penetration testing ▪ **Resilience:** Maintain secure offline backups; test disaster recovery plans regularly.
Third party and supply chain management Manage privacy and security risks from third party relationships, including hospitals, cloud providers, and vendors.	▪ Due diligence for onboarding vendors handling personal information ▪ Contractual protections including data protection obligations and audit rights ▪ Regular vendor security assessments ▪ Management of overseas service providers and cross-border transfers ▪ Incident notification requirements in vendor contracts ▪ Vendor off-boarding procedures ensuring secure data return or destruction ▪ Register of third parties with data access, including sub processors ▪ Ongoing monitoring of vendor compliance.	▪ **Due diligence:** Assess vendor security posture and certifications ▪ **Agreements:** Include contractual protections specifying security requirements, breach notification and indemnities ▪ **Standards:** Communicate minimum cybersecurity standards for vendors ▪ **Breach coordination:** Establish plans for responding to vendor breaches.
Incident response and data breach management Prepare a detailed breach response plan for swift, effective incident management	▪ Development and testing of a comprehensive data breach response plan ▪ Procedures for breach containment, investigation and remediation ▪ Assessment criteria for notifiable data breach (**NDB**) scheme thresholds ▪ Templates for OAIC notification within required timeframes ▪ Protocols for notifying affected individuals.	▪ **Incident response team:** Create cross-functional team with defined roles and external contacts ▪ **Breach playbook:** Document procedures for detection, containment, assessment, notification and recovery ▪ **Notification templates:** Draft pre-approved templates for OAIC and affected individual communications ▪ **Escalation protocols:** Establish thresholds for identifying and escalating suspected incidents ▪ **Contractual audit:** Review contracts to identify breach notification obligations ▪ **Containment procedures:** Document procedures to isolate systems and preserve evidence ▪ **Impact assessment:** Develop criteria to assess 'eligible data breach' thresholds ▪ **Testing:** Conduct annual tabletop exercises; document lessons learned ▪ **Post-incident review:** Create methodology for root cause analysis and corrective actions.

Key requirement	Focus areas	Recommended actions
Privacy-by-design and AI / data innovation Embed privacy and security into new products and technologies from the design phase.	▪ Integration of privacy and cybersecurity checkpoints in product development ▪ PIAs during design phase for new technologies ▪ Data minimisation; use of anonymised or synthetic data where feasible ▪ Transparent disclosure of AI use in healthcare products ▪ TGA compliance for software/AI classified as medical devices ▪ Continuous evaluation of AI models for privacy impacts and bias ▪ Monitoring of AI-specific regulations and governance frameworks.	▪ **Design checks:** Integrate privacy and cybersecurity into development; conduct PIAs ▪ **Minimisation:** Use anonymised or synthetic data where feasible ▪ **Regulatory compliance:** Ensure TGA compliance for software/AI medical devices ▪ **Evaluation:** Continuously evaluate AI models for privacy impacts and bias.
Training and awareness Build a culture of privacy and security through regular training.	▪ Privacy training for all staff on Privacy Act requirements and data handling ▪ Cybersecurity awareness training on phishing, ransomware and social engineering ▪ Specialised workshops for teams handling sensitive data ▪ Clear internal guidance on privacy and security questions ▪ Regular evaluation of training effectiveness with annual updates ▪ Role-specific training for developers, clinicians and third-party management.	▪ **Privacy training:** Train all staff on Privacy Act requirements and data handling ▪ **Cybersecurity training:** Conduct regular cyber awareness training ▪ **Specialised workshops:** Provide targeted training for teams handling sensitive data ▪ **Guidance:** Post clear internal guidance on privacy and cybersecurity ▪ **Refresh:** Evaluate training effectiveness and update annually.
Monitoring, auditing and continuous improvement Establish ongoing processes to monitor compliance and continuously improve.	▪ Periodic internal and external audits of privacy and security controls ▪ Active vulnerability management with prompt patching and annual penetration testing ▪ Tracking of all incidents including near-misses; analysis for patterns ▪ Monitoring of regulatory developments from OAIC and other regulators ▪ Policy updates for Privacy Act reforms and evolving guidance ▪ Continuous improvement with action plans following audits or incidents ▪ Up-to-date documentation to demonstrate compliance.	▪ **Audits:** Conduct periodic internal and external audits for APP compliance ▪ **Vulnerability management:** Maintain active patching and annual penetration testing ▪ **Incident monitoring:** Track all incidents and near-misses; analyse for patterns ▪ **Regulatory watch:** Monitor OAIC developments; update policies for Privacy Act reforms ▪ **Continuous improvement:** Implement action plans following audits or incidents ▪ **Documentation:** Maintain current records to demonstrate compliance.

2.2

Artificial intelligence and intellectual property in life sciences R&D

How AI is reshaping inventorship, ownership and infringement risks

Lead author:
Zeina Milicevic, Partner

"AI is accelerating discovery in life sciences, but the legal frameworks governing inventorship and authorship are structured to protect human innovation and creativity."

Zeina Milicevic

Chapter summary

AI is rapidly transforming research and development in the life sciences sector. AI applications range from machine learning and neural networks for drug discovery to product development.

AI presents a significant market opportunity by reducing the time and cost of R&D. AI can assist in collecting, analysing, interpreting and presenting key data throughout the R&D process. These improvements in efficiency and capability expand the possibilities for innovation and growth across the life sciences sector.

*However, the growing use of AI in research raises complex intellectual property questions. Patent and copyright frameworks are structured to protect inventions and creative works produced by humans. As AI systems play a greater role in generating research outputs, uncertainty arises regarding inventorship, authorship and ownership of valuable research and development (**R&D**) assets.*

This chapter examines how existing intellectual property law applies to AI-assisted innovation in life sciences research. It considers recent international developments, the implications for patent and copyright protection and practical steps organisations can take to protect their intellectual property and mitigate infringement risks when using AI systems.

Introduction

AI is increasingly embedded throughout the life sciences R&D pipeline. Machine learning models are used to identify potential drug targets, while predictive analytics can assist in optimising clinical trial design. AI systems are also used to analyse complex genomic and biomedical datasets, enabling researchers to extract insights from large volumes of scientific data. In addition, automated tools are increasingly deployed to support molecule design and optimisation, helping accelerate the early stages of drug discovery.

These technologies offer significant commercial opportunities by accelerating discovery and improving research efficiency. For example, the global market for AI-enabled drug discovery is projected to grow substantially over the next decade as pharmaceutical and biotechnology organisations invest in data-driven innovation.

However, the increasing reliance on AI tools raises important questions about how intellectual property law applies where AI is involved in creation.

Impact on intellectual property protection

Courts around the world have begun to consider whether inventions generated with the assistance of AI can be protected under existing patent frameworks.

Inventorship refers to the individual who is recognised as having created a patentable invention. **Authorship** refers to the individual who is recognised as having created an original work, relevant to copyright protection. **Ownership** refers to who holds the legal right to exploit or commercialise the resulting IP – which may differ from the inventor or author.

CASE STUDY

DABUS litigation – can an AI system be a patent inventor?

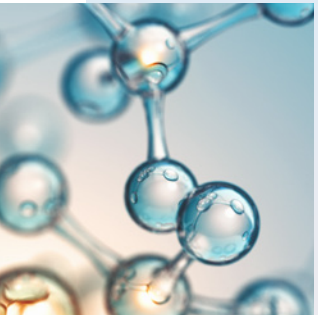
Computer scientist Stephen Thaler[60] filed patent applications in several jurisdictions naming an AI system known as DABUS (Device for the Autonomous Bootstrapping of Unified Sentience) as the sole inventor.

The applications were intended to test whether existing patent frameworks could recognise AI-generated inventions.

In Australia, the Federal Court initially held that an AI system could be listed as an inventor. However, the decision was overturned on appeal in *Commissioner of Patents v Thaler*,[61] where the Full Federal Court held that the *Patents Act 1990 (Cth)* requires an inventor to be a natural person. The Full Court reached this decision primarily through statutory construction and also considered the history of patent law and its role in rewarding human ingenuity.

Dr Thaler subsequently sought special leave to appeal to the High Court, which was refused.

Courts in the US, the UK and the EU have reached similar conclusions.



LESSON

AI-generated inventions still require human inventorship

As it stands, Australian law requires that a patent inventor be a natural person. This means that an AI system or AI tool cannot be named as an inventor on a patent application. Any change in this position would require legislative reform.

In litigation, when faced with a question of who is the true inventor of a patent, a key consideration is whether a person has materially contributed to the invention having regard to the quality, rather than the quantity, of the contribution. This framework may guide the approach to how courts consider the question of AI contributions to innovations.

For life sciences organisations using AI-assisted discovery tools, organisations may wish to ensure that research workflows document human contributions that may support inventorship claims in future patent applications.

> *"As AI becomes embedded in life sciences R&D, protecting innovation will increasingly depend not only on patents, but on how organisations structure data governance, trade secrets and human oversight."*
>
> Zeina Milicevic

Copyright law and authorship

Copyright is another important intellectual property right that can arise in research and development activities.

Copyright protects literary and artistic works, including materials commonly generated in scientific research such as:

- research notes;
- datasets and databases;
- data visualisations and charts; and
- analytical tools and reports.

Consequently, copyright can be key to protecting data that supports research, but that may not appear in the patent application itself.

Under the *Copyright Act 1968 (Cth)*, copyright subsists only in works created by a human author. Works generated entirely by AI systems without human involvement are therefore unlikely to attract copyright protection.

This creates potential risks for organisations that rely heavily on AI systems to generate research outputs. Copyright law differs from patent law in that copyright protection arises automatically upon creation of a work. There is no requirement to register copyright (or name an author upon creation). This means that questions of whether a work has a human author may not arise until an enforcement dispute.

The level of human contribution required for copyright protection in AI-assisted works remains uncertain. Using tools in creation is not new and does not preclude copyright protection. However, the human creator must contribute sufficient 'independent intellectual effort'. With AI-generated works, it is unclear what level of human contribution will satisfy this authorship requirement.

Overseas jurisdictions are also grappling with this question. For example, the United States Copyright Office refused copyright registration for an AI-generated artwork created using extensive prompting, concluding that the work lacked sufficient human authorship.[62] By contrast, a Chinese court has found that prompt selection and parameter choices may constitute sufficient human input to support copyright protection.[63]

These divergent outcomes highlight the evolving and uncertain nature of copyright protection for AI-generated materials.

Strategic considerations for securing IP protection

In the current legal environment, life sciences organisations should take proactive steps to ensure that AI-assisted innovation remains capable of attracting intellectual property protection.

Practical measures may include:

- identifying which stages of research workflows require meaningful human involvement to support inventorship or authorship;
- maintaining contemporaneous records documenting human contributions to inventions and research outputs;
- implementing internal policies governing the use of AI tools in R&D processes; and
- auditing research workflows to assess whether outputs treated as proprietary assets involve sufficient human input to support intellectual property protection.

Alternative strategies for protecting AI-generated innovation

Where patent or copyright protection may be uncertain, organisations should consider adopting a multi-layered intellectual property strategy.

Trade secrets and confidential information can play an important role in protecting valuable research assets, including proprietary datasets, algorithms and technical know-how.

Unlike patents, trade secrets do not require public disclosure and can remain protected indefinitely, provided the information remains confidential and continues to provide a competitive advantage.

Survey results indicate that **70%** of organisations have established formal governance frameworks to address IP and data ownership risks in AI.

To maintain trade secret protection, organisations should:

- identify and clearly classify confidential research assets;
- restrict access to sensitive information on a need-to-know basis;
- implement robust confidentiality agreements with employees and collaborators; and
- adopt contractual controls when sharing proprietary information with research partners.

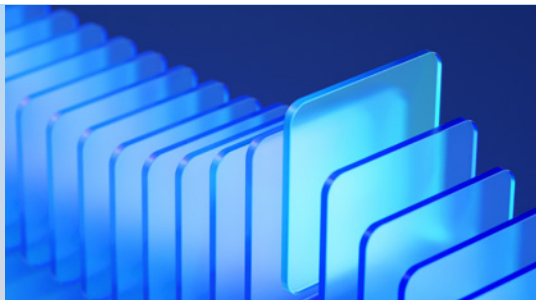
IP infringement risks associated with AI systems

The use of AI tools in research can also create intellectual property infringement risks.

These risks may arise both during the development of AI systems and when organisations use AI-generated outputs.

AI models are typically trained using vast datasets that may include copyright-protected materials. Whether the use of such materials for training purposes constitutes copyright infringement remains an unresolved legal question in Australia.

On the output side, AI-generated materials may reproduce or closely resemble copyrighted works or patented inventions contained in the training data. Organisations that subsequently use or distribute these outputs may expose themselves to infringement risk.



To mitigate these risks, organisations should consider:

- conducting due diligence on AI tools and their training data sources;
- reviewing contractual arrangements with AI providers;
- implementing internal guidance governing the use of AI tools and prompts; and
- establishing governance frameworks for AI-assisted innovation and content generation.

Practical guidance: Protecting IP in AI-enabled R&D

Life sciences organisations integrating AI into research programs should consider adopting structured governance frameworks to manage intellectual property risks.

Key measures may include:

- documenting human contributions to inventions generated with AI tools;
- establishing internal policies governing the use of AI systems in R&D;
- implementing contractual protections with AI vendors and research partners;
- maintaining robust trade secret protection for proprietary datasets and algorithms; and
- regularly reviewing AI-assisted research workflows to ensure intellectual property protection remains available.

As AI becomes increasingly embedded in scientific discovery, organisations that proactively address intellectual property risks will be better positioned to protect their innovations and maintain competitive advantage.

2.3
AI governance and regulatory risk

Privacy, liability and regulatory risks arising from AI deployment

Lead authors: Sonja Read, Partner, Zeina Milicevic, Partner and Chelsea Gordon, AI Lead – Legal

Chapter summary

AI is increasingly embedded across the life sciences sector, supporting drug discovery, clinical research, diagnostics and patient care. While these technologies offer significant opportunities to accelerate innovation and improve healthcare outcomes, they also introduce new legal, regulatory and operational risks.

Unlike intellectual property questions surrounding AI-assisted inventions, which are considered in the previous chapter, this chapter focuses on the governance and regulatory implications of deploying AI systems in practice. In Australia, AI is currently regulated through a complex patchwork of existing legal frameworks rather than a dedicated AI statute. Privacy law, consumer protection law, therapeutic goods regulation, workplace safety obligations and sector-specific regulation may all apply depending on how AI systems are used.

> *AI governance is rapidly shifting from a voluntary best practice to an emerging regulatory expectation across the life sciences sector."*
>
> Chelsea Gordon

Introduction

AI is increasingly deployed across the life sciences sector, supporting clinical research, diagnostics, patient care and operational decision-making. While these technologies offer significant opportunities to improve healthcare outcomes and accelerate innovation, their adoption also introduces new legal, regulatory and operational risks.

Unlike the previous chapter, which focuses on intellectual property issues arising from AI-assisted innovation, this chapter examines the governance and regulatory implications of deploying AI systems in practice.

In Australia, AI is currently regulated through a complex patchwork of existing legal frameworks rather than a dedicated AI statute. Privacy law, consumer protection law, therapeutic goods regulation, workplace safety obligations and sector-specific regulation may all apply depending on how AI systems are used.

The evolving regulatory landscape in Australia

AI regulation varies significantly across jurisdictions.

In Europe, the **EU AI Act** introduces a comprehensive risk-based regulatory framework governing the development and deployment of AI systems. In the US, regulatory responses have emerged at both federal and state levels, including California's **Transparency in Frontier AI Act**, which focuses on accountability for advanced AI systems.

Australia has adopted a different approach. Rather than introducing standalone AI legislation, the Australian Government has signalled a preference for a **principles-based regulatory model** that relies primarily on existing legal frameworks.

The National AI Plan[65], released in December 2025, confirms the Government's intention to maintain a relatively light-touch regulatory approach designed to encourage investment and innovation.

Under this approach, AI systems are regulated indirectly through existing laws, including:

- privacy legislation;
- consumer protection law;
- copyright law;
- workplace health and safety law;
- sector-specific regulatory frameworks; and
- online safety regulation.

The Government has indicated that targeted regulatory reforms may occur where necessary to address specific AI-related risks.

For example, in October 2025 the Commonwealth Treasury released findings from a review examining whether the Australian Consumer Law (**ACL**) is fit for purpose in addressing risks arising from AI systems.[66]

At the same time, regulators are increasingly examining how existing regulatory frameworks apply to AI technologies within the health and life sciences sectors. The Department of Health and the Therapeutic Goods Administration (**TGA**) have both undertaken consultations regarding regulatory updates for AI-enabled medical technologies.

As a result, organisations operating in the life sciences sector must navigate a dynamic regulatory environment in which legal obligations may evolve rapidly.

95% of the leaders surveyed reported their organisation is using AI. The most common uses are:

1. Regulatory submissions/ compliance monitoring.
2. Clinical trial design or patient testing.
3. Commercial operations (marketing, sales).
4. Drug discovery and development.
5. Medical devices or diagnostic tools.

Insight: AI governance is becoming a core compliance issue

Although Australia does not yet have a standalone AI statute, regulatory scrutiny of AI systems is increasing. Organisations deploying AI technologies must therefore ensure that existing legal frameworks – particularly those relating to privacy, consumer protection and product safety – are appropriately integrated into their governance structures.

For life sciences organisations, AI governance is no longer solely a technical or operational issue. It is increasingly a core compliance and risk management function requiring coordinated oversight across legal, regulatory, clinical and technology teams.

> *"In practice, AI governance is not about the technology itself – it's about how organisations manage data, oversight and accountability around the systems they deploy."*
>
> Sonja Read

Key legal risks associated with AI deployment

The deployment of AI technologies in the life sciences sector can create several categories of legal risk beyond intellectual property issues.

Survey results show that product safety and data privacy AI governance frameworks are relatively well-established.

However, many organisations have not yet established formal AI governance frameworks addressing workforce capability and human oversight **(60%)**, third-party / vendor AI risk **(59%)**, or bias, ethics and regulatory risk **(57%)**.

Privacy risks

The use of personal information in AI systems presents significant privacy risks. Organisations that handle personal information are subject to the *Privacy Act 1988 (Cth)* (**Privacy Act**), which imposes obligations on Australian Privacy Principle (**APP**) entities regarding the collection, use, disclosure and security of personal information.

Civil penalties for serious or repeated interferences with privacy under the Privacy Act can reach the greater of A$50 million, three times the value of the benefit obtained, or 30% of adjusted turnover during the breach period.

Recent amendments to the Privacy Act introduced through the *Privacy and Other Legislation Amendment Act 2024 (Cth)* have further expanded regulatory exposure by introducing a statutory tort for serious invasions of privacy. Individuals may now bring civil proceedings where their privacy has been intentionally or recklessly invaded in circumstances where they had a reasonable expectation of privacy.

Because life sciences organisations frequently handle highly sensitive health information, the use of such data to train AI systems represents a particularly high-risk activity.

Surveillance law risks

Certain AI systems may involve the recording or analysis of audio or visual data. These activities may be regulated by state-based surveillance legislation.

For example, the *Surveillance Devices Act 2007 (NSW)* restricts the use of listening devices to record private conversations without consent. Similar laws apply in other Australian jurisdictions.

AI technologies such as clinical documentation tools ('AI scribes'), facial recognition systems or video-based diagnostic tools may therefore raise surveillance law compliance issues.

Consumer protection risks

AI-generated outputs may create risks under the ACL where organisations fail to disclose that services involve AI systems or fail to adequately communicate the limitations of those systems.

In certain circumstances, inaccurate or misleading AI-generated information could give rise to claims of misleading or deceptive conduct. In serious cases, civil penalties may reach the greater of A$50 million, three times the value of the benefit obtained, or 30% of adjusted turnover during the breach period.

Therapeutic goods regulation

Where AI is incorporated into medical devices, it may fall within the regulatory category of Software as a Medical Device (**SaMD**).

Manufacturers and sponsors must ensure that such devices are appropriately assessed by the Therapeutic Goods Administration before they can be supplied in Australia. This includes demonstrating the safety, performance and ongoing monitoring of AI-enabled systems.

Failure to comply with these obligations may constitute a breach of the *Therapeutic Goods Act 1989 (Cth)* (the **TG Act**) and attract significant civil or criminal penalties.

Workplace and operational risks

The implementation of AI systems may create additional workforce risks in the life sciences sector. Where the use of an AI system poses work health and safety risks, a person conducting a business or undertaking (**PCBU**) has a duty to eliminate or minimise risks so far as reasonably practicable.[67]

For example, recent reforms in New South Wales impose additional obligations where digital work systems – including AI, algorithms or automated platforms – are used to allocate or manage work.

These provisions are intended to prevent technologies from imposing unsafe workloads or enabling unreasonable workplace surveillance.

To comply with these obligations, organisations should review their work health and safety policies and ensure they are aligned with internal AI governance frameworks and acceptable use policies.

Ethical and research risks

AI technologies used in clinical research may raise ethical considerations relating to participant consent, fairness and transparency.

Human research in Australia is subject to oversight by Human Research Ethics Committees (**HREC**s). The introduction of AI systems into clinical trials may therefore require additional approvals and disclosures.

AI-driven participant recruitment tools may also create risks of unintended bias or discrimination if training datasets are not appropriately representative.

Product liability risks

AI-enabled products and services may give rise to emerging product liability risks. In the US, litigation involving AI-powered technologies is beginning to test whether traditional product liability frameworks apply to AI systems. For example, *Garcia v Character Technologies, Inc* has raised questions about whether AI systems may be treated as a 'product' for the purposes of liability analysis.[68]

Similarly, in T*aylor v Intuitive Surgical* [69], a court found that a clinician may not be solely responsible for harm arising from the use of a robotic surgical system. The manufacturer was found to have breached its duty to warn the hospital purchaser about risks associated with the system.

While the position under Australian law remains uncertain, these developments highlight the potential for liability to extend beyond clinicians to technology developers and manufacturers where AI-enabled systems contribute to clinical decision-making.

CASE STUDY

AI training data and de-identification

In July 2025, the Office of the Australian Information Commissioner (**OAIC**) examined whether I-MED Radiology Network breached the Privacy Act when medical imaging data was shared with the healthcare AI organisation Harrison.ai for the purpose of training diagnostic algorithms.

The investigation considered whether the disclosure breached APP 6, which governs the use and disclosure of personal information. The OAIC ultimately concluded that the data had been sufficiently de-identified and therefore did not constitute personal information under the Privacy Act.

LESSON

De-identification is critical for AI training datasets

The investigation highlights the importance of robust data governance when using health information to train AI systems. Organisations should ensure that AI training datasets are appropriately de-identified and supported by clear governance frameworks, contractual safeguards and documented data handling processes.

CASE STUDY

AI-generated medical advice and consumer protection risk

In January 2026, reports emerged that Google's 'AI Overview' search functionality had provided incorrect medical information in response to queries relating to pancreatic cancer and liver disease.

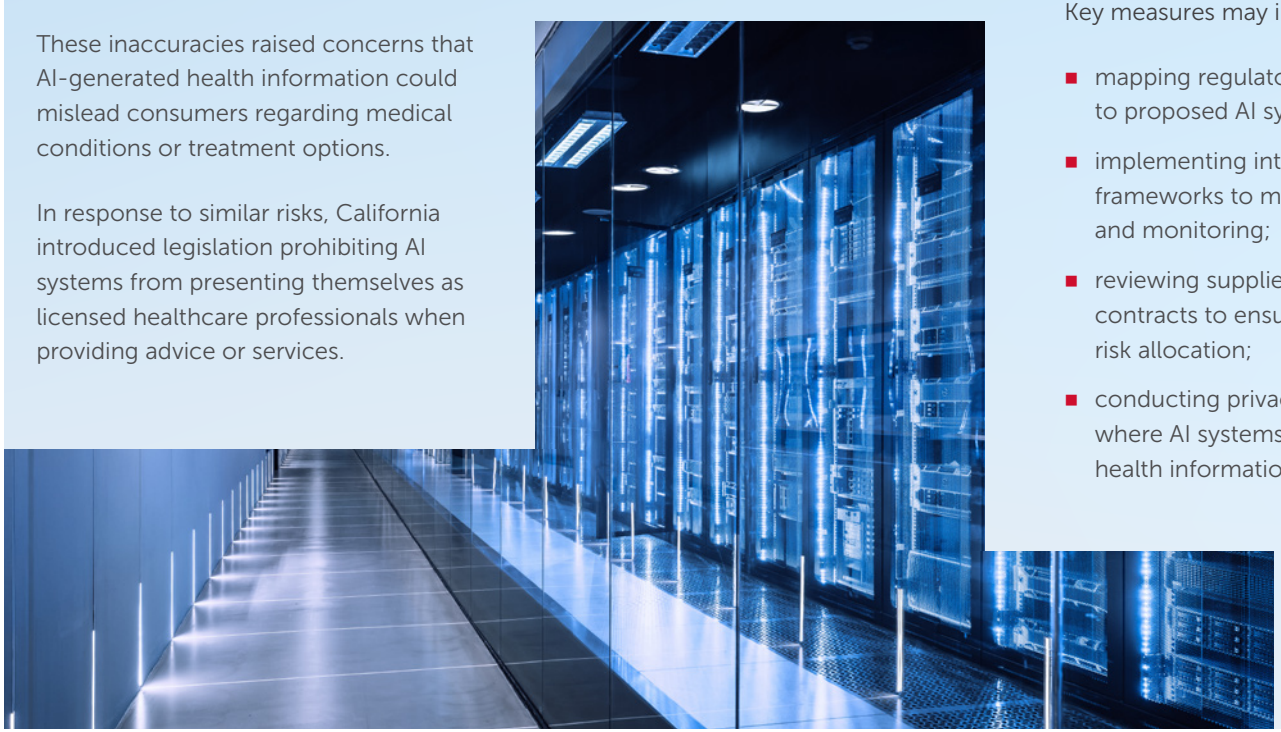
These inaccuracies raised concerns that AI-generated health information could mislead consumers regarding medical conditions or treatment options.

In response to similar risks, California introduced legislation prohibiting AI systems from presenting themselves as licensed healthcare professionals when providing advice or services.

LESSON

Transparency is essential when AI systems interact with patients

Organisations deploying AI-enabled health technologies should ensure that users clearly understand when they are interacting with an AI system and the limitations of AI-generated outputs.



Practical guidance: AI governance for life sciences organisations

To manage the legal risks associated with AI deployment, life sciences organisations should consider implementing structured AI governance frameworks.

Key measures may include:

- mapping regulatory obligations relevant to proposed AI systems and use cases;
- implementing internal AI governance frameworks to manage risk identification and monitoring;
- reviewing supplier and technology contracts to ensure appropriate risk allocation;
- conducting privacy impact assessments where AI systems process personal or health information;
- developing internal policies governing the use of AI systems in research and clinical contexts;
- ensuring that employees receive guidance on appropriate use of AI technologies; and
- reviewing insurance coverage to determine whether AI-related risks are adequately addressed.

As AI becomes increasingly embedded in scientific discovery and healthcare delivery, organisations that proactively address governance and regulatory risks will be better positioned to protect patients, maintain regulatory compliance and realise the benefits of AI-driven innovation.

2.4

Insurance gaps and dispute exposure

Why many organisations discover coverage gaps too late

Lead author:
Kemsley Brennan, Partner

"Many life sciences organisations discover gaps in their insurance cover only after a claim arises. Proactive review of insurance programs is critical to managing litigation and regulatory risk."

Kemsley Brennan

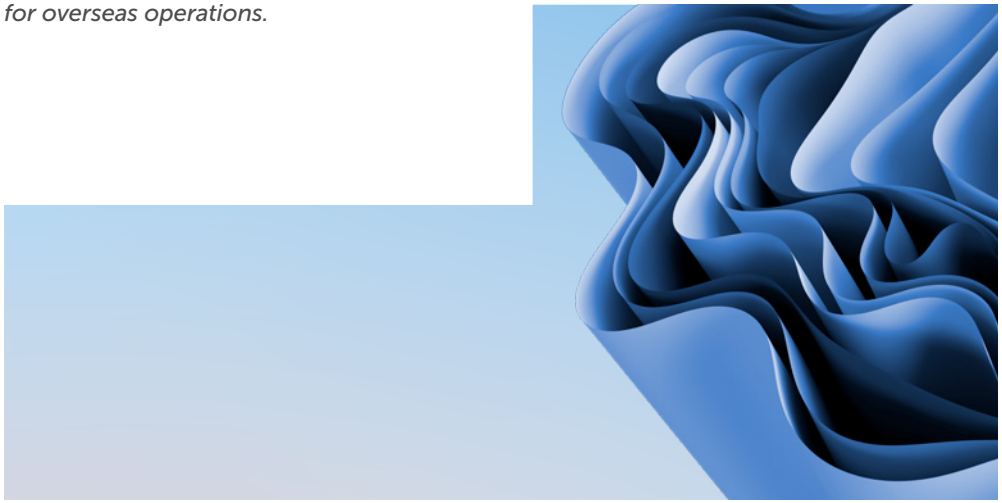
Chapter summary

Insurance plays a critical role in managing the litigation, regulatory and operational risks faced by life sciences organisations. Pharmaceutical, biotechnology, medical device and digital health organisations operate in a highly regulated environment where product liability claims, clinical trial disputes, shareholder actions and cyber incidents can lead to substantial financial exposure.

Despite this risk landscape, many life sciences organisations discover only after a claim arises that their insurance programs contain significant gaps in coverage. Policies may exclude key activities such as clinical trials, professional services or product recalls, or may contain territorial limitations that restrict cover for overseas operations.

As the preceding chapters illustrate, life sciences organisations operate within an increasingly complex legal and regulatory risk landscape. Insurance therefore plays a critical role in transferring and managing the financial consequences of these risks when disputes or regulatory actions arise.

This chapter outlines the key insurance coverages that life sciences organisations should consider and highlights common coverage gaps. It also provides practical guidance for reviewing insurance programs, managing policy exclusions and ensuring that coverage limits remain appropriate as businesses expand into new markets or technologies.



Introduction

Life sciences organisations operate in a complex risk environment shaped by regulatory oversight, scientific uncertainty and global markets. Litigation risks may arise from product safety concerns, clinical trial outcomes, regulatory investigations or shareholder claims. At the same time, emerging risks such as cyber-attacks and data breaches create additional exposures.

Insurance is therefore an essential component of risk management for organisations operating across the pharmaceutical, biotechnology and medical technology sectors. However, insurance programs must be carefully structured to ensure that they respond appropriately to the specific risks faced by life sciences businesses.

Standard corporate insurance policies are rarely sufficient on their own. Life sciences organisations typically require a combination of specialised policies designed to address risks arising throughout the product development lifecycle, from early-stage research through to product commercialisation.

Insight: Insurance gaps often emerge only after a claim

A common challenge for life sciences organisations is that insurance coverage gaps are only discovered once litigation or regulatory action has commenced. Exclusions relating to clinical trials, professional services or contractual liabilities may significantly reduce the protection provided by otherwise comprehensive policies.

Regular review of insurance programs – particularly when organisations expand internationally, launch new products or begin clinical trials – is therefore essential to ensure coverage remains aligned with the organisation's evolving risk profile.

Key insurance coverages in the life sciences sector

A comprehensive insurance program for life sciences organisations typically includes several specialised coverages designed to address different categories of risk.

General liability insurance

General liability insurance forms the foundation of most corporate insurance programs. It typically provides cover for third-party claims arising from bodily injury or property damage caused by the organisation's activities.

However, these policies often contain exclusions relevant to life sciences organisations, including exclusions relating to clinical trials, professional services or contractual liabilities. Organisations should therefore review policy wording carefully to ensure key exposures are not excluded.

Product liability insurance

Product liability insurance provides protection against claims arising from the design, manufacture or distribution of pharmaceutical products, biotechnology products or medical devices.

These policies typically respond to third-party claims alleging that a product caused injury or harm to consumers.

For organisations distributing products internationally, it is important that product liability policies provide worldwide territorial coverage, particularly where products are supplied into high-litigation jurisdictions such as the US.

Clinical trials liability insurance

Clinical trials liability insurance provides coverage for risks associated with clinical research involving human participants. Policies generally cover compensation claims arising from death, bodily injury or illness suffered by participants during the course of a clinical trial.

These policies are typically written on a claims-made basis, meaning coverage is triggered when a claim is first made and notified during the policy period.

Clinical trials policies should ideally include broad coverage for:

- participant injury compensation;
- defence costs;
- settlement payments; and
- medical expenses arising from trial participation.

Many policies also extend coverage to additional insured parties such as contract research organisations, investigators, clinical trial sites and ethics committees.

Directors' and officers' liability insurance

Directors' and officers' (D&O) liability insurance protects company directors and senior executives against claims arising from alleged wrongful acts committed in their management capacity.

D&O policies typically include three forms of cover:

- **Side A cover** – protection for individual directors and officers;
- **Side B cover** – reimbursement for the company when it indemnifies directors; and
- **Side C cover** – entity coverage for claims brought directly against the company.

Life sciences organisations face heightened D&O risk due to volatile clinical trial outcomes, capital-raising pressures and regulatory scrutiny.

CASE STUDY

Mayne Pharma Group Limited – D&O insurance limits under pressure

In 2024, the ASX-listed pharmaceutical company Mayne Pharma Group Limited agreed to settle a shareholder class action for approximately A$38 million, without admitting liability.[70]

Insurance covered only A$4.7 million of the settlement, leaving the organisation to fund the remainder.

LESSON

D&O policy limits may be insufficient for major shareholder litigation

The case illustrates the importance of stress-testing D&O policy limits against potential shareholder class actions, regulatory investigations and market disclosure claims.

Professional indemnity insurance

Professional indemnity insurance provides cover for claims alleging financial loss arising from negligent advice or professional services.

In the life sciences sector, this may include services such as:

- clinical trial management;
- research services;
- laboratory testing; and
- consulting or advisory services.

Product liability policies frequently exclude professional services claims, meaning that a separate professional indemnity policy is often necessary.

Intellectual property insurance

Life sciences organisations frequently face risks relating to alleged infringement of intellectual property rights, including patents, trademarks, designs or copyright.

Intellectual property insurance can provide coverage for defence costs and damages arising from third-party claims alleging infringement of intellectual property rights.

Although some limited coverage may be available under general liability policies, many organisations obtain standalone intellectual property insurance to ensure more comprehensive protection.

Product recall insurance

Product recall insurance provides coverage for costs associated with recalling defective products from the market. These costs may include:

- regulatory notification;
- product retrieval and disposal;
- transportation and logistics;
- crisis management and communications; and
- business interruption losses.

Product recall insurance is particularly important in the pharmaceutical and medical device sectors where regulatory authorities may require urgent market withdrawal of products.

The **Therapeutic Goods Administration's updated recall procedures**, introduced in March 2025, have increased regulatory expectations regarding product recall readiness in Australia.

Cyber liability insurance

Life sciences organisations increasingly hold large volumes of sensitive data, including patient records, clinical trial data and proprietary research information.

Cyber liability insurance provides protection against losses arising from cyber incidents such as data breaches, ransomware attacks or system disruptions.

Traditional property or liability policies often exclude cyber-related incidents, meaning that a dedicated cyber insurance policy is typically required.

CASE STUDY

Merck – cyber insurance disputes following the NotPetya attack

In 2017 a cyber-attack involving the NotPetya malware caused approximately US$1.4 billion in losses for pharmaceutical company Merck & Co.[71]

Merck's insurers initially declined coverage under an 'acts of war' exclusion contained in its insurance policies. The dispute resulted in significant litigation before the matter was eventually resolved through settlement.

LESSON

Cyber policy exclusions can materially affect coverage

The dispute highlights the importance of carefully reviewing cyber insurance policy wording, particularly exclusions relating to cyber warfare or state-sponsored attacks.

Managing policy exclusions and coverage gaps

Insurance policies frequently contain exclusions, limitations or special conditions that may significantly affect coverage.

For example, insurers may exclude liability assumed under contract beyond ordinary legal obligations. This can create gaps where organisations provide broad indemnities or performance guarantees to commercial partners.

Organisations should therefore review insurance policies carefully to identify exclusions relating to:

- specific products or components;
- known safety concerns;
- contractual indemnities;
- professional services; and
- clinical trials activities.

Where possible, organisations may seek to negotiate narrower exclusions or obtain additional endorsements from insurers.

Ensuring coverage for global operations

Life sciences organisations often operate internationally through clinical trials, overseas manufacturing arrangements or product distribution networks.

Insurance policies should therefore be reviewed to ensure that territorial coverage extends to all relevant jurisdictions.

Some policies restrict coverage to Australia and New Zealand or exclude claims arising in the US due to higher litigation risks. Where organisations operate globally, it may be necessary to arrange international insurance programs or obtain local policies in relevant jurisdictions.

Foreign regulatory regimes may also impose insurance requirements. For example, the EU Medical Devices Regulation (**EU MDR**) requires manufacturers to maintain 'sufficient financial coverage' for potential liability claims.

Claims notification and policy conditions

Many insurance policies operate on a claims-made basis, meaning that coverage depends on notifying the insurer of claims or potential claims during the policy period.

Organisations should notify insurers as soon as practicable of any circumstances that could give rise to a claim. These may include serious customer complaints, regulatory investigations or adverse clinical trial events.

Prompt notification is critical because failure to notify circumstances within the policy period may result in coverage being denied.

In some situations, legal advice may be helpful when preparing notifications to ensure that potential claims are captured appropriately under the policy.

Setting appropriate policy limits

Determining appropriate insurance limits requires careful consideration of the organisation's risk profile.

Organisations should regularly review coverage limits with their insurance brokers and advisers, particularly where the organisation:

- launches new products;
- expands into new markets;
- outsources manufacturing;
- begins new clinical trials; and
- handles increasing volumes of patient data.

Insurance limits should also account for the possibility that multiple related claims may be aggregated under a single policy limit.

Where defence costs are included within policy limits, prolonged litigation can quickly erode available coverage.

Practical guidance: Insurance coverage checklist

The following checklist summarises key governance measures that life sciences organisations should consider when reviewing their insurance programs and identifying potential coverage gaps.

For life sciences organisations operating in a highly regulated and litigation-sensitive environment, insurance should be treated as a strategic risk management tool rather than an administrative procurement exercise. Regular review of insurance coverage, policy limits and exclusions is essential to ensure that coverage evolves alongside the organisation's operational, regulatory and geographic risk profile.

Key action items	Implementation	Practical notes/examples
Confirm that all key life science risks are insured	Organisations should ensure they carry the full suite of policies relevant to their operations, including (as applicable): ■ public and product liability ■ clinical trials liability ■ D&O liability ■ professional indemnity (particularly for R&D, testing or advisory activities) ■ cyber liability ■ product recall and contamination insurance ■ intellectual property infringement insurance.	Life sciences organisations face a broader risk landscape than most industries. Standard public and product liability insurance is rarely sufficient alone. Verify you hold the full spectrum of policies a life sciences business needs. Address common gaps with the specialist coverages below.
Consider specialist coverage: Clinical trials liability	Organisations should consider whether the organisation holds clinical trials liability insurance for all current and planned trials, across all phases and jurisdictions. Review territorial limits, indemnity limits and participant injury wording for compliance with ethics committee and regulatory requirements.	Regulators and ethics committees often require clinical trials liability cover. Policies may only respond to Australian trials unless they expressly include overseas sites. Gaps commonly arise when organisations expand trials internationally without updating insurance.
Consider specialist coverage: D&O liability	Organisations should review any D&O policy coverages including additional coverages, limits, sub-limits and exclusions, and policy conditions against the organisation's capital structure, disclosure obligations and regulatory exposure. It is important to stress test the policy limits against potential shareholder class actions and regulatory investigation and prosecution scenarios.	In 2024, Mayne Pharma Group Limited (ASX: MYX) settled a shareholder class action for AU$38 million (without admitting liability). Insurance covered only AU$4.7 million – the organisation funded the balance. This highlights the consequences of insufficient D&O policy limits and the importance of appropriate limit adequacy for shareholder class action exposure.
Consider specialist coverage: Professional indemnity	Organisations should confirm whether the business provides R&D, testing, design, advisory or consultancy services (including to third parties). If so, organisations should consider whether these activities fall under a professional indemnity policy or product liability policy.	Product liability insurers commonly exclude professional services claims unless the organisation holds separate cover – a frequent gap for biotech and medtech organisations engaged in contract research or advisory work.
Consider specialist coverage: Cyber liability	Organisations should consider whether they require dedicated cyber insurance. It may be insufficient to rely on property, 'all-risks' or general liability policies. Consider whether the policy responds to data breaches (including patient and trial data), ransomware and extortion, business interruption, incident response and forensics, legal and regulatory response costs, notification and credit monitoring, and third-party liability claims. Review any exclusions (e.g. war or state-sponsored attack), sub-limits, waiting periods and notification requirements. Align internal incident response procedures with policy conditions. It is also important not to attach cyber liability as an endorsement to a general policy; cyber insurance should typically be structured as a standalone policy.	Life sciences organisations hold highly sensitive data including patient records and clinical trial results. Traditional liability policies usually do not respond to cyber incidents. In 2017, Merck suffered ~US$1.4 billion in losses from the NotPetya cyber-attack. Insurers denied cover under an 'acts of war' exclusion – underscoring the need to scrutinise cyber policy language.

Key action items	Implementation	Practical notes/examples
Consider specialist coverage: Product recall and contamination	It is important to review whether product liability policies exclude recall and contamination costs. Where necessary, obtain dedicated recall and contamination insurance covering first party recall expenses and associated business interruption losses.	Product liability insurance often excludes recall and correction costs. The TGA's updated Procedure for Recalls, Product Alerts and Product Corrections took effect on 5 March 2025 – recall readiness and insurance are more important than ever.
Review intellectual property infringement insurance	It is important to ensure that the life science organisation has intellectual property insurance that will provide cover for breach of intellectual property rights	There may be some cover for intellectual property breaches under the General Liability policy but such cover is usually very limited. Obtaining a standalone Intellectual Property policy is a prudent approach.
Scrutinise exclusions and contractual assumptions of risk	Organisations should conduct a detailed review of policy exclusions, limitations and conditions – focusing on known defects, specific components, ingredients and jurisdictions. Cross check insurance cover against indemnities and guarantees in commercial contracts.	Insurers generally do not cover liabilities you assume under contract beyond ordinary legal duties. If broad indemnities or performance guarantees are not specifically endorsed by the insurer, they will not be covered.
Ensure coverage matches global operations	It is important to consider territorial limits and jurisdictional exclusions across all policies. Confirm coverage extends to overseas trials, customers and subsidiaries. Assess compliance with foreign regulatory insurance requirements and arrange local or global programs where needed.	Some insurers limit cover to Australia and New Zealand or exclude the US due to litigation risk. Foreign regulations may impose additional requirements – e.g. the EU MDR[72] requires 'sufficient financial coverage' for liability.
Manage claims and notifications proactively	Organisations should implement internal escalation procedures for complaints, investigations, adverse events and potential circumstances which may give rise to claims. Notify insurers as soon as practicable of any circumstance that may give rise to a claim. Ensure compliance with all policy conditions.	Insurers write many policies on a claims-made basis. Timely notification of circumstances that may give rise to a claim is critical to preserving coverage.
Set adequate policy limits	Organisations should seek advice from their insurance broker to set policy limits. Consider excess or umbrella layers to protect against catastrophic losses. Review limits regularly as the business evolves.	Some policies aggregate multiple related claims into a single 'occurrence,' meaning one policy limit applies to what could otherwise be numerous claims. This may reduce deductibles but can be dangerous if limits are inadequate for mass claims. Where defence costs erode limits, prolonged litigation can quickly exhaust coverage and therefore an annual assessment of limits of insurance of each policy which forms the insurance program is essential.

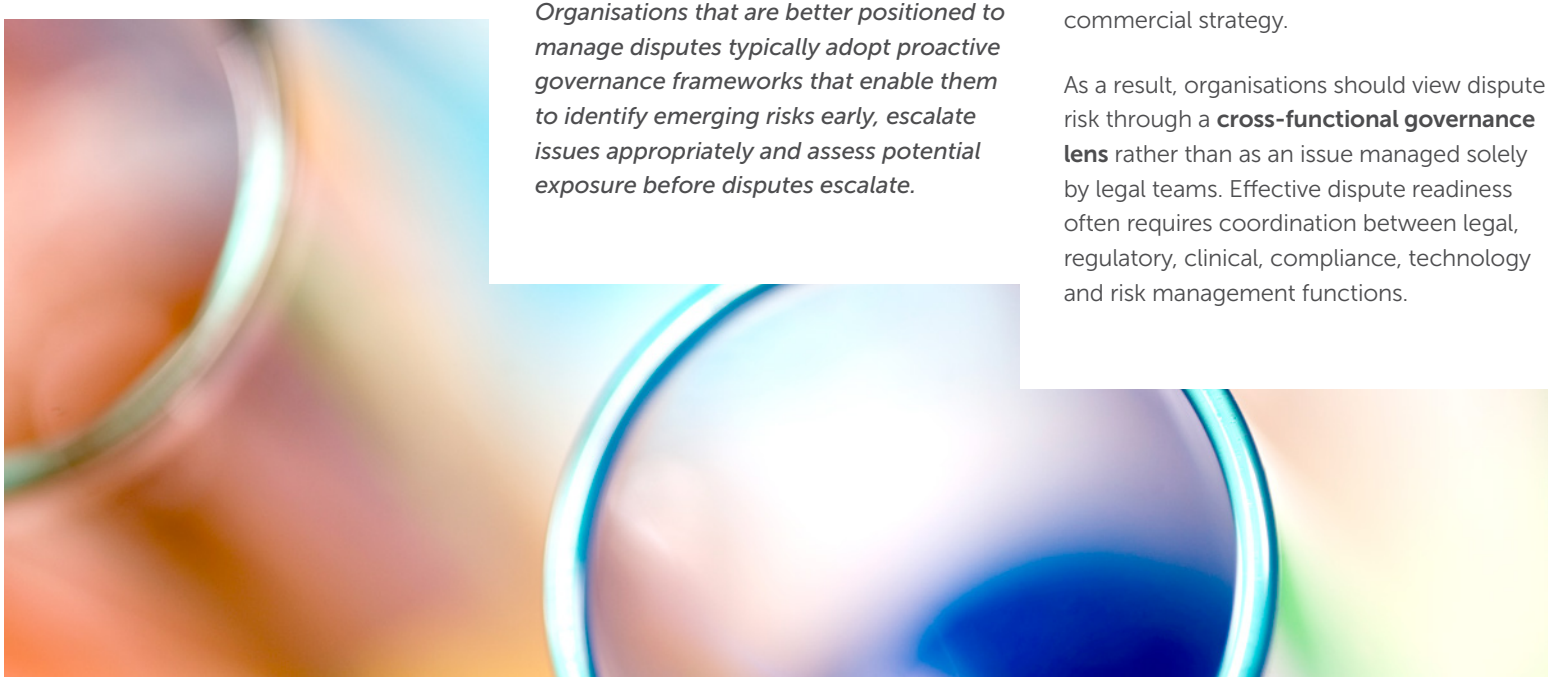
Part III – Strategic considerations for life sciences organisations

As regulatory scrutiny intensifies and technological innovation accelerates, life sciences organisations must adapt their governance, risk management and compliance frameworks.

The following chapters explore practical strategies that organisations can adopt to manage emerging legal risks, strengthen regulatory compliance and mitigate the likelihood of future disputes.

3.1 Dispute readiness for life sciences organisations

How organisations can identify early warning signals and assess dispute exposure.



Life sciences organisations are operating in an environment characterised by increasing regulatory scrutiny, rapid technological innovation and expanding litigation risk. As the preceding chapters illustrate, disputes in the sector may arise from a wide range of sources, including regulatory enforcement, product safety concerns, clinical trial outcomes, privacy incidents, intellectual property disputes and the deployment of emerging technologies such as AI.

In this environment, effective dispute management requires more than reactive legal responses once litigation begins. Organisations that are better positioned to manage disputes typically adopt proactive governance frameworks that enable them to identify emerging risks early, escalate issues appropriately and assess potential exposure before disputes escalate.

Disputes are increasingly complex and interconnected

Many disputes in the life sciences sector arise not from a single legal issue but from the interaction of multiple regulatory, technological and operational factors.

For example, a cyber incident affecting patient data may trigger privacy enforcement action, regulatory scrutiny, contractual disputes with research partners and potential shareholder litigation. Similarly, issues arising during clinical trials may lead to regulatory investigations, product liability claims and reputational consequences affecting commercial strategy.

As a result, organisations should view dispute risk through a **cross-functional governance lens** rather than as an issue managed solely by legal teams. Effective dispute readiness often requires coordination between legal, regulatory, clinical, compliance, technology and risk management functions.

Identifying early warning signals

In many cases, disputes are preceded by warning signs that initially appear as operational or regulatory issues rather than legal problems.

Examples of early warning indicators may include:

- adverse clinical trial events or unexpected safety signals;
- regulatory correspondence or requests for information;
- significant product complaints or quality issues;
- cybersecurity incidents or attempted intrusions;
- internal whistleblower reports or compliance concerns;
- disputes with research partners, suppliers or contract research organisations; and
- negative media coverage or public criticism of clinical or data practices.

Organisations that establish clear escalation pathways for such issues are often better able to assess potential legal exposure before disputes escalate into formal litigation or regulatory proceedings.

Strengthening governance and escalation frameworks

A key element of dispute readiness is ensuring that organisations have governance structures capable of identifying and responding to emerging risks.

Effective governance frameworks typically include:

- clearly defined internal escalation procedures for legal and regulatory issues;
- cross-functional committees overseeing compliance, data governance and emerging technologies;
- board or executive oversight of significant regulatory and litigation risks; and
- defined processes for responding to regulatory inquiries or investigations.

These governance structures help ensure that emerging issues are evaluated through both operational and legal perspectives before they develop into disputes.

Integrating legal oversight into technology deployment

As the earlier chapters illustrate, many emerging disputes in the life sciences sector arise from the use of new technologies, particularly in areas such as AI, digital health platforms and large-scale health data analytics.

Legal and compliance teams should therefore be involved early when organisations deploy technologies that may affect patient data, clinical decision-making or medical device functionality.

Early legal involvement can assist organisations in identifying regulatory obligations, managing intellectual property issues and mitigating privacy or consumer law risks before technologies are deployed at scale.

Reviewing insurance and risk transfer strategies

Insurance remains an important mechanism for managing the financial consequences of disputes. However, as discussed in the preceding chapter, coverage gaps may only become apparent once litigation or regulatory proceedings commence.

Organisations should therefore regularly review their insurance programs to ensure that coverage aligns with evolving risks. Particular attention may be required where organisations:

- conduct clinical trials in multiple jurisdictions;
- launch new therapeutic products or medical devices;
- deploy AI-enabled technologies or digital health platforms;
- handle large volumes of sensitive health data; and
- expand into new markets with different regulatory environments.

Regular engagement with insurance brokers and advisers can help ensure that coverage limits, exclusions and territorial scope remain appropriate as the organisation's risk profile evolves.

Questions for legal counsel and executive teams

In addition to formal governance frameworks, life sciences organisations may benefit from periodically assessing dispute readiness by considering key strategic questions.

Dispute readiness area	Questions for organisations and leaders
Governance and oversight	■ Are potential legal and regulatory risks escalated to legal counsel early in the decision-making process? ■ Does the organisation have clear internal procedures for managing regulatory inquiries and investigations? ■ Is there effective communication between legal, regulatory, technology and clinical teams?
Data governance and technology deployment	■ How are privacy, cybersecurity and AI governance risks assessed when deploying new technologies? ■ Are data governance frameworks aligned with evolving privacy and cybersecurity expectations? ■ Are appropriate contractual protections in place when sharing data with research partners or technology providers?
Regulatory preparedness	■ How does the organisation monitor evolving regulatory expectations from bodies such as the Therapeutic Goods Administration (**TGA**), the Office of the Australian Information Commissioner (**OAIC**) and the Australian Competition and Consumer Commission (**ACCC**)? ■ Are internal compliance frameworks regularly reviewed against emerging regulatory risks?
Insurance and financial exposure	■ Do current insurance policies adequately cover the organisation's key operational risks, including cyber incidents, clinical trials and product liability? ■ Have policy limits been stress-tested against potential litigation scenarios?

Insight: Dispute readiness is becoming a strategic capability

For life sciences organisations, dispute readiness is increasingly a strategic capability rather than a reactive legal function.

Organisations that proactively identify emerging risks, strengthen governance frameworks and integrate legal oversight into operational decision-making are generally better positioned to manage disputes efficiently and protect long-term commercial value.

In an environment where regulatory expectations are evolving rapidly and technological innovation is accelerating, dispute readiness will remain an essential component of effective risk management across the life sciences sector.

3.2

Looking ahead: the future of disputes in life sciences

How emerging dispute trends are shaping strategy, investment and innovation

Lead author: Simone Mitchell, Partner and Life Sciences Lead

"The regulatory and technological landscape facing life sciences organisations is evolving rapidly. Dispute readiness will increasingly depend on how effectively organisations integrate governance, compliance and innovation."

Simone Mitchell

The dispute landscape for life sciences organisations in Australia is evolving rapidly. Scientific innovation, expanding regulatory oversight and the growing use of digital technologies are creating new opportunities for the sector while simultaneously increasing legal complexity.

As the preceding chapters illustrate, disputes in the life sciences sector are no longer confined to traditional areas such as patent litigation or product liability claims. Organisations are increasingly encountering disputes arising from regulatory enforcement, data governance, cybersecurity incidents and the deployment of emerging technologies such as AI.

Looking ahead, several developments are likely to shape the future dispute environment for the life sciences sector. These trends are likely to influence not only how disputes arise, but also how organisations structure governance frameworks, manage regulatory risk and make strategic investment decisions.

Privacy reform and the expanding regulation of health data

One of the most significant developments likely to affect the life sciences sector in the coming years is the continued evolution of Australia's privacy framework. Organisations operating in this sector routinely collect and analyse highly sensitive information, including clinical trial data, patient health records and genetic information. As digital health technologies and data-driven research become increasingly central to innovation, regulatory scrutiny of how this information is handled is expected to intensify.

The next phase of reforms to Australia's privacy framework – commonly referred to as the **'tranche 2' reforms** – is expected to progress during 2026. Earlier government consultation processes and responses to the Privacy Act Review indicate that these reforms may significantly reshape Australia's privacy regime, with potentially substantial operational implications for organisations handling sensitive health information.

One proposed reform is the introduction of a **'fair and reasonable' test** governing the handling of personal information. Under this model, organisations may be required to demonstrate that their collection, use and disclosure of personal information is fair and reasonable in the circumstances, even where consent has been obtained.

For life sciences organisations, this reform could have important implications for activities such as:

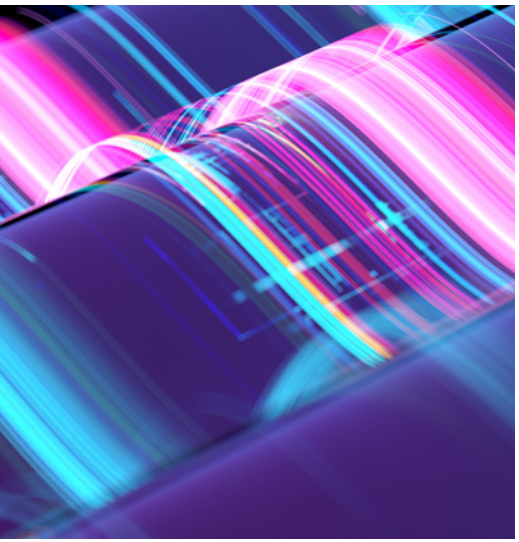
- clinical trials and research programs;
- patient support initiatives;
- digital health platforms and connected medical devices; and
- large-scale health data analytics projects.

Further reforms may also introduce **expanded individual rights**, such as rights relating to the deletion of personal information or objections to certain forms of data processing. In addition, proposals to broaden the definition of personal information may expand the categories of information subject to privacy regulation, particularly in relation to online identifiers and device-generated data.

Another proposal is the potential **removal of the small business exemption**, which could bring a larger number of health technology start-ups and emerging life sciences organisations within the Privacy Act framework for the first time.

Implication for organisations:

Life sciences organisations should begin preparing for a more demanding privacy regulatory environment by strengthening data governance frameworks, reviewing consent and data-use practices, and ensuring that privacy and cybersecurity considerations are embedded in technology and research initiatives.



AI and emerging technology disputes

AI is rapidly becoming embedded across the life sciences sector, from drug discovery and clinical research to diagnostics and digital health platforms. While these technologies offer significant opportunities to accelerate innovation and improve healthcare outcomes, they also raise new legal and regulatory questions.

As AI systems play a greater role in clinical decision-making, data analysis and patient interaction, disputes may arise in areas such as:

- liability for AI-assisted clinical decisions;
- regulatory classification of AI-enabled medical devices;
- governance of training datasets and data ownership;
- IP rights; and
- transparency and accountability in automated decision-making.

Courts and regulators globally are only beginning to address these issues, meaning that legal frameworks will likely continue evolving as AI technologies become more widely deployed across healthcare systems.

Implication for organisations:

Organisations deploying AI technologies should ensure that governance frameworks address both technical and legal risks, including data governance, IP rights, transparency obligations and regulatory compliance for AI-enabled medical technologies.

Increasing regulatory scrutiny across the sector

Regulatory oversight of the life sciences sector is also expected to continue intensifying. Regulators in Australia – including the Therapeutic Goods Administration (**TGA**), the Office of the Australian Information Commissioner (**OAIC**) and the Australian Competition and Consumer Commission (**ACCC**) – have increasingly demonstrated a willingness to pursue enforcement action where regulatory obligations are not met.

This trend reflects broader policy objectives relating to consumer protection, patient safety and the governance of emerging technologies. As regulatory expectations evolve, organisations may face greater scrutiny of areas such as clinical trial conduct, advertising practices, product safety monitoring and the handling of health information.

Regulatory investigations may increasingly precede or accompany litigation, meaning that disputes may emerge from regulatory processes rather than traditional commercial conflicts.

Implication for organisations:

Life sciences organisations should ensure that compliance frameworks remain aligned with evolving regulatory expectations and that internal escalation processes allow potential issues to be addressed before they develop into formal enforcement proceedings.

Cross-border disputes and global litigation exposure

Life sciences disputes are also becoming increasingly international in nature. Pharmaceutical products, medical devices and digital health platforms frequently operate across multiple jurisdictions, exposing organisations to regulatory oversight and litigation risk in different legal systems.

For example, product liability claims relating to pharmaceuticals or medical devices may involve coordinated proceedings across multiple countries. Similarly, cyber incidents affecting health data may trigger regulatory investigations and litigation in several jurisdictions simultaneously.

These developments mean that organisations must increasingly consider legal risk through a global lens, particularly where products, clinical trials or data platforms operate across borders.

Implication for organisations:

Organisations should ensure that governance frameworks, regulatory strategies and insurance programs account for cross-border dispute exposure and the potential for coordinated international regulatory investigations.

Preparing for a more complex dispute environment

Taken together, these developments suggest that disputes in the life sciences sector will continue to evolve alongside scientific and technological innovation.

For organisations operating in this environment, legal risk management will increasingly require a proactive and integrated approach. This may include:

- strengthening governance frameworks across legal, regulatory and technology functions;
- monitoring emerging regulatory developments in areas such as privacy and AI;
- implementing robust data governance and cybersecurity measures; and
- ensuring that insurance programs reflect evolving technological and regulatory risks.

Ultimately, organisations that integrate legal risk management into their broader innovation and governance strategies will be better positioned to manage disputes and navigate the complex regulatory environment shaping the future of the life sciences sector.

Final insight: Disputes will increasingly follow innovation

The life sciences sector has long been defined by scientific and technological innovation. New therapies, medical technologies and research methods continue to transform healthcare outcomes and create significant opportunities for growth. Yet as innovation accelerates, so too does the complexity of the legal and regulatory environment surrounding it.

Disputes are increasingly emerging at the intersection of science, technology and regulation. For life sciences organisations, the challenge will be ensuring that governance, compliance and risk management frameworks evolve at the same pace as the innovations they support.

Organisations that anticipate emerging risks, strengthen oversight and integrate legal risk management into their innovation strategies will be best positioned to navigate the disputes landscape ahead.

For organisations operating at the intersection of healthcare, science and technology, dispute readiness will increasingly be defined not by how disputes are defended, but by how effectively risks are anticipated and managed before disputes arise.

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About MinterEllison

MinterEllison is Australia's leading independent law firm enhanced by specialist consulting.

Our dedicated, full-service, multidisciplinary life sciences team advise across the life sciences product and business lifecycle – from concept to commercialisation, and beyond.

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[5] Hardeman v. Monsanto Co., No. 19-16636 (9th Cir. 2021) :: Justia
[6] Pilliod v. Monsanto Co. :: 2021 :: California Courts of Appeal Decisions :: California Case Law :: California Law :: U.S. Law :: Justia
[7] Managing the Roundup™ Litigation | Bayer Global
[8] Johnson v. Monsanto Co. :: 2020 :: California Courts of Appeal Decisions :: California Case Law :: California Law :: U.S. Law :: Justia (*Johnson* case which discusses Monsanto/Bayer's reliance on EPA early opinion that glyphosate carcinogen causation was inconclusive) ; Managing the Roundup™ Litigation | Bayer Global (Bayer website maintaining denial that glyphosate is carcinogenic); Glyphosate | US EPA (current EPA webpage which maintains the EPA's position that glyphosate is not carcinogenic)
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[15] Product Liability Pelvic Mesh: Complications, Lawsuits, & Settlements | Chicago Personal Injury Attorney | Thomas Plouff
[16] Transvaginal Mesh Timeline | Boston Product Liability Lawyers
[17] *In re: American Medical Systems, Inc. Pelvic Repair System Products Liability Litigation*, MDL No. 2325 (S.D. W. Va.).
[18] *In re: Ethicon, Inc. Pelvic Repair Systems Products Liability Litigation*, MDL No. 2327 (S.D. W. Va.).
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[30] *Karpik v Carnival Plc* [2023] HCA 39
[31] *Kathy Even, et al. v. Alcon Laboratories Inc., et al., Case No. 1:25-cv-00574*, in the U.S. District Court for the District of Colorado
[32] *Diane Dyess v. Novo Nordisk Inc., Case No. 2:25-cv-00546*, in the U.S. District Court for the Eastern District of Pennsylvania
[33] *Stewart, et al. v. Aeropres Corp., et al., Case No. 1:23-cv-13207*, in the U.S. District Court for the Northern District of Illinois
[34] Tepezza Lawsuit: Hearing Loss Claims & Lawsuit Updates
[35] NEC Baby Formula Lawsuit | Latest Verdicts and Settlement
[36] https://www.fedcourt.gov.au/law-and-practice/practice-documents/practice-notes/gpn-undr
[37] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2018] FCA 1556
[38] Sigma Pharmaceuticals (Australia) Pty Ltd v Wyeth [2018] FCA 1556
[39] https://www.fedcourt.gov.au/law-and-practice/practice-documents/practice-notes/cpn-1
[40] https://www.fedcourt.gov.au/law-and-practice/practice-documents/practice-notes/ip-1
[41] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters
[42] https://www.tga.gov.au/news/media-releases/new-transparency-measures-prescription-medicines
[43] www.tga.gov.au/sites/default/files/prescription-medicines-transparency-measures.pdf
[44] An *organisation* means: (a) an individual; (b) a body corporate; (c) a partnership; (d) any other unincorporated associated; or (e) a trust; that is not a small business operator, a registered political party, an agency, a State or Territory authority or a prescribed instrumentality of a State or Territory (Privacy Act, s 6C).
[45] A *health service* is defined as: An activity performed in relation to an individual is a health service if the activity is intended or claimed (expressly or otherwise) by the individual or the person performing it: (a) to assess, maintain or improve the individual's health; (b) where the individual's health cannot be maintained or improved – to manage the individual's health; (c) to diagnose the individual's illness, disability or injury; (d) to treat the individual's illness, disability or injury or suspected illness, disability or injury; or (e) to record the individual's health for the purposes of assessing, maintaining, improving or managing the individual's health (Privacy Act, s 6FB).
[46] Privacy Act, Sch 1.
[47] Privacy Act, s 6.
[48] Privacy Act, s 6.
[49] Privacy Act, s 6FA.
[50] *Health Records and Information Privacy Act 2002* (NSW), *Health Records Act 2001* (Vic) and *Health Records (Privacy and Access)* Act 1997 (ACT).
[51] *Facebook Inc v Australian Information Commissioner* [2022] FCAFC 9.
[52] *Gebo Investments (Labuan) Ltd v Signatory Investments Pty Ltd* [2005] NSWSC 544, [33].
[53] *Australian Securities and Investments Commission v ActiveSuper Pty Ltd* (No 1) [2012] FCA 1519 at [47].
[54] *OAIC, Australian Privacy Principles guidelines – Chapter B: Key concepts*, see here: http://www.oaic.gov.au/privacy/australian-privacy-principles/australian-privacy-principles-guidelines/chapter-b-key-concepts.
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[59] https://www.cyber.gov.au/business-government/asds-cyber-security-frameworks/essential-eight
[60] *Thaler v Commissioner of Patents* [2021] FCA 879
[61] *Commissioner of Patents v Thaler* [2022] FCAFC 62
[62] *Second Request for Reconsideration for Refusal to Register Théâtre D'opéra Spatial* (Copyright Review Board, Sept. 5, 2023)
[63] *Li v. Liu* (Beijing Internet Court, Nov. 27, 2023)
[64] CA's SB 53, EU AI Act are both governance frameworks, but the similarities end there | IAPP
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[67] *Work Health and Safety Amendment (Digital Work Systems) Act 2026* (NSW)
[68] Washington Supreme Court Extends Medical-Device Manufacturers' Duty to Warn - Washington Legal Foundation
[69] Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 528 (2017)
[70] https://www.supremecourt.vic.gov.au/sites/default/files/2024-08/Notice%20of%20Proposed%20Settlement.pdf
[71] Merck & Co, Inc, et al. v. ACE American Insurance Company, et al. No. UNN-L-2682-18
[72] EU Medical Device Regulation (MDR 2017/745), Article 10(16)

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