

Sparke•Helmore

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Sparkebeat

Australia's Legal Environment – Health Law Update

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Introduction

Welcome to the sixteenth issue of the Health Update – Sparkebeat – where Sparke Helmore's market leading national Health team brings you the latest in local news and knowledge from across Australia and abroad.

This edition explores a range of emerging legal, regulatory and risk issues shaping the healthcare, insurance and life sciences sectors. We examine the growing prevalence of psychological injury and nervous shock claims, the challenges these claims present for insurers and policymakers, and the continuing debate around balancing fair compensation with a sustainable liability framework. With the dramatic increase in diagnosis and treatment of ADHD, we consider the regulatory and clinical challenges associated with medications. We also provide an update on the Monash IVF litigation and the broader regulatory reforms being implemented across the fertility sector in response to high-profile incidents.

We also highlight significant regulatory developments affecting healthcare providers, including new obligations for cosmetic medicine practitioners, evolving requirements for advertising prescription medicines, and major health law reforms in Queensland. We also consider the increasing cyber risk facing healthcare organisations, drawing lessons from recent high-profile data breaches and outlining key considerations for providers, insurers and underwriters.

Rounding out the edition is an overview of reforms designed to improve access to healthcare in rural and remote communities, including changes that will expand prescribing rights for appropriately qualified nurses.



We hope you find this issue informative and useful. If there are any topics you would like us to cover in the future, please contact Marie-Clare Elder at marie-clare.elder@sparke.com.au.

Marie-Clare Elder
National Service Line Leader - Health

Sparke Helmore's national Health team

Our health team advises medical defence organisations, insureds (including hospitals, clinics, practitioners and other medical and allied health service providers), insurers, underwriting agencies cover holders and brokers, both locally and internationally including in the Lloyd's market.

Our team specialises in clinical negligence litigation, investigations, professional conduct hearings, and coronial inquiries. We also advise on matters related to regulatory compliance, policy drafting, coverage and indemnity issues.

This unique experience allows us to meet the needs of our clients regardless of jurisdiction, volume or complexity.

Royal Commission into AI announced

Authors: Jason Kwan (Partner) and Lani Carter (Special Counsel)

South Australian Premier, Peter Malinauskas, has announced that South Australia will launch a Royal Commission into Artificial Intelligence (**AI**).

The Premier says that the technology presents opportunities but warns that unchecked development could pose risks to society and the future of work.

The Commissioners will examine the impacts of AI on a number of areas – including health.

The government intends to appoint a panel of commissioners with relevant expertise to lead the Royal Commission. The Commission is expected to hear evidence and receive submissions from a broad cross-section of the South Australian community, including business, industry bodies, unions, technology developers, academics, independent experts and representatives of creative industries.

The Commission has been announced to commence on 1 October 2026 and is expected to be finalised 1 July 2027.

How healthcare businesses and insurers can prepare

Businesses located in South Australia using AI can take steps now in preparation for the Royal Commission:

1. Consider how your business and employees are using AI. Are you familiar with all of the uses and are there appropriate policies in place regulating the use of AI. Healthcare businesses should also consider whether appropriate consents and disclosures are in place.
2. Privacy implications – do you understand the privacy risks and are there safeguards and policies in place to protect personal information?
3. AI governance – does your organisation have in place structures and policies to ensure the oversight and management of AI?
4. Businesses may wish to make a proactive submission to the commission, or may be called upon to make submissions, provide evidence or attend as a witness. Businesses ought to identify who in the business has expertise in this area and how a response will be coordinated if your business is called upon.
5. If you would like to give broader thought to the issues arising in AI in the healthcare space, see our previous publications on the implications of AI in the healthcare space:

    When AI joins the consultation: the legal implications of AI scribes in healthcare

The Trust deficit: AI's hidden perils in healthcare claims and insurance

Revisiting the regulation of Artificial Intelligence Medical Devices



How Sparke Helmore can assist

Sparke Helmore has a team of health and technology specialists with experience representing clients called before Royal Commissions including the Aged Care Royal Commission and the Disability Royal Commission.

We are monitoring the terms of reference and developments of the Royal Commission, and we are ready to assist clients to respond to requests for information or to give evidence before the Commission.

Reach out to Marie-Clare Elder about how we can assist.

ADHD medication: regulatory and clinical challenges

Author: Mark Sainsbury (Partner)

Attention-Deficit/Hyperactivity Disorder (**ADHD**) now effects more than one million Australians and is estimated to cost the economy around $20 billion annually. In line with increased rates of diagnosis, treatment rates have also increased dramatically over the past 25 years or so from around two people per 1,000 receiving medication in the year 2000 up to 22 people per 1,000 in 2024.

In line with the increase in these numbers, governments and medical bodies have responded and recent reforms in Queensland, New South Wales, Western Australia and the ACT (collectively **state and territory governments**) have expanded a general practitioner's (**GP**) ability to initiate or continue psychostimulant treatment for patients. However, these rules are not uniform across the different Australian jurisdictions.

From 1 December 2025, all specialist GPs in Queensland were able to initiate, modify and continue psychostimulant medication for adults with ADHD within the existing maximum dose limits. Paediatricians also had their authorisations extended to enable them to prescribe psychostimulants to young adults aged 18 to 24 years.

The changes reflect a national shift towards community-based ADHD management and it is hoped that these changes will:

(a) reduce referral bottlenecks and wait lists

(b) enable a more integrated and accessible ADHD care through general practice

(c) strengthen continuity of care for Queenslanders with ADHD, particularly during the transition from adolescents to adulthood

(d) benefit people in regional and remote areas where access to specialist services can be limited, and

(e) reduce wait times and financial barriers helping more Queenslanders access the care that they require.

It is clear how these changes will dramatically benefit patients located in regional and remote areas. Previously, patients faced substantial access barriers to diagnosis and treatment as they may have faced lengthy wait times for specialist appointments in the larger cities.

It should be noted that these changes only apply to adult ADHD diagnoses and prescribing, and paediatric ADHD care continues for children.

Despite the benefits from the expanded authorities, medical indemnity insurers and state and territory governments have issued guidelines for GPs and other medical professionals with respect to the prescribing of psychostimulants.

Further, medical indemnity insurers have been quick to caution their members to continue practising within their scope of expertise and to be conscious that the diagnosing of ADHD requires careful clinical assessment, excluding differential diagnoses and managing comorbidities such as anxiety, depression or substance use disorders. It is also noted that initiating psychostimulant medication carries risks involving cardiovascular effects, dependency concerns and potential misuse.

Medical indemnity insurers ought to ensure that GPs understand the rules for their applicable state or territory and undertake diagnosis and treatment appropriately. Anecdotally in that regard, complaints to the Office of the Health Ombudsman in Qld and to Ahpra have increased with respect to the prescribing of ADHD medication to patients and issues arising from taking the prescribed medication.

Medical practitioners and their insurers are also concerned with the increased uptake in telehealth and the prescribing of psychostimulants over that platform. This is made more complex by the availability of interstate telehealth options as a prescription for ADHD medication may not be valid unless the prescriber meets all the requirements of every jurisdiction involved, meaning where the practitioner is located, where the patient is and where the prescription will be dispensed.

Another complexity identified by industry bodies is where parents are operating under family law provisions and a child requires treatment. This can be problematic if one parent objects to the prescription of ADHD medication .

It is perhaps some of the potential side effects of this medication that is giving rise to concern amongst some GPs and patients. The typical medication being prescribed is psychostimulant medicine which is defined as a schedule 8 medicine in Queensland and includes Dexamphetamine, Lis Dexamphetamine or other types of amphetamine or methylphenidate. These are classified as restricted medicines, high risk medicines, diversion risk medicines and monitored medicines. These medications can have specific health risks, which in rare cases, can induce psychosis.

The most commonly prescribed ADHD drug in Australia is Vyvanse and this is currently under investigation by the Therapeutic Goods Administration (**TGA**) following a spike in adverse events reported for the medication. In response, the producer of the drug has informed the TGA that the formula has not changed and that strict quality controls are in place and therefore there is no reason for a patient to stop taking the drug if it is working for them.

It should be pointed out, of course, that an increase in adverse events being reported does coincide with a substantial increase in prescriptions in the broader community. There is also some speculation about the role of social media in relation to adverse event reporting given the huge increase in discourse on social media platforms relating to ADHD and prescriptions.

In the first six months of 2026, adverse events recorded in relation to Vyvanse numbered 320, which compares to only nine reports in the prior six months. Adverse events reported included ineffectiveness of the medication, anxiety and insomnia.

The recorded increase in Australia is reflected globally on the World Health Organisation's equivalent global database which has also shown an uptake in reports relating to the active ingredient of Vyvanse being Lis Dexamphetamine. In terms of complaints versus prescriptions, Vyvanse prescriptions have almost doubled from around 960,000 in 2022 to approximately 1.8 million in 2024 according to the Pharmaceutical Benefits Scheme.



It is also recognised that some patients with comorbidities risk mania or psychosis when taking Vyvanse particularly if they took more than prescribed, which is a risk that general practitioners must be aware of and educate their patients on.

In that regard, a Royal Australian College of General Practitioners' (**RACGP**) spokesperson (Dr Tim Jones) commented recently that the issues go well beyond medication because the adverse event reporting aligns with a 'pretty astronomical' increase in prescriptions for ADHD stimulants. Dr Jones stated that colleagues in the public psychiatry arena were also reporting more mental health admissions relating to prescribed stimulants often triggered by episodes of psychosis, anxiety and insomnia. He considers this is entering into serious territory for side effects and that it is a wake-up call to the general safety of stimulants.

In relation to other unintended implications from ADHD medication use, a well-publicised example is in the aviation industry where the Australian safety regulator, Civil Aviation Safety Authority (**CASA**), has refused to issue medical certificates to would-be pilots because they have a diagnosed condition of ADHD that involves treatment by methylphenidate (Ritalin).

One pilot challenged CASA's decision and received a successful outcome in the Administrative Review Tribunal. However, the decision was appealed by CASA to the Federal Court, where it was decided that CASA had broad safety related powers under the legislation and it was within their scope to decline to issue a licence to the applicant on safety grounds because it was not definitively known whether exposure to high altitudes influences the metabolism of methylphenidate so that the risk to the safety of air navigation could neither be evaluated nor managed.

Looking ahead, we expect practitioners and industry bodies will await the outcome of the TGA's investigation into the Vyvanse adverse events and, potentially, flowing from that we may see further guidelines and education programs for practitioners rolled out by the government, industry bodies and medical indemnity insurers.

However, the reforms that have happened in Queensland and other eastern states are unlikely to be reduced or repealed. Both South Australia and Western Australia have watched the Queensland/ New South Wales reforms closely and have now announced ADHD training programs that they will require GPs to complete before additional prescribing authorities are granted.

In that regard, the RACGP continues to advocate for nationally consistent approaches to ADHD reform because in their view, fragmented state-by-state regulations create unnecessary complexity for both practitioners and patients and no doubt increase risk of non-compliance with the requirements and perhaps misuse of the prescribing powers in certain circumstances.

This is a developing space and should be closely monitored by practitioners impacted by the changes, their professional indemnity insurers and lawyers who act for those practitioners and insurers in defence of complaints and claims.



Snapshot:
An update on the Monash IVF litigation

Authors: Kerri Thomas (Partner) and Dinah Amrad (Associate)

Critical laboratory errors thrust Monash IVF into the spotlight after two separate embryo mix-ups occurred last year. In its Brisbane clinic, a patient was mistakenly implanted with a different couple's embryo, leading to the birth of a child genetically unrelated to the mother. Separately, in its Melbourne clinic, a patient's treatment protocol was breached as her own embryo was transferred back to her, rather than implanting her partner's embryo.

Following up on our previous article covering these incidents (see Sparkebeat Issue 14 November 2025) earlier this year, Monash IVF reached financial settlements (amount undisclosed) with the families involved in the two separate embryo mix-ups.

Victoria's Health Regulator has also completed its investigation into the incidents and decided to impose conditions on Monash IVF's registration which focus on matters such as ensuring the integrity and traceability of genetic material through comprehensive consent and documentation processes, rigorous verification and patient checks, accurate recording in management systems, and strengthened staff capability. These conditions will remain in force until the Health Regulator is satisfied that the risks identified are effectively mitigated and Monash IVF has demonstrated sustained compliance.

Monash IVF is no stranger to lawsuits, having been involved in a separate, highly publicised $56 million class action settlement late last year arising from disputed genetic testing practices.

A lawsuit was commenced by more than 700 former patients, alleging that Monash IVF used faulty, non-invasive genetic screening test on live embryos (called Non-invasive Preimplantation Genetic Testing for Aneuploidy (niPGT-A)) between May 2019 and October 2020, which lead to inaccurate tests that incorrectly flagged viable embryos as abnormal, leading patients to discard embryos that might have led to viable pregnancies.

Takeaway points

To restore public trust in fertility treatments, the Australian fertility industry is taking active steps to implement comprehensive regulatory reforms. The Victorian government for one, is tightening regulations by amending laws and introducing legislation with the aim of making IVF clinics safer and more accountable. Some of these amendments empower the State's Health Minister to personally intervene to cancel a provider's registration.

Interestingly, the incidents have also generated complex legal questions concerning who actually holds legal and parental rights when a woman carries and gives birth to a child who is genetically unrelated to her. It highlights failures in informed consent and creates issues over whether or not patients have reasonable grounds to argue they were not properly warned about the risk of false positives or procedural human errors during treatment planning.

Major changes for cosmetic medicine: understanding your obligations from November 2026

Authors: Marie-Clare Elder (Partner) and Kate Hodgkinson (Senior Associate)

With the cosmetic industry firmly in the sites of the Australian Health Practitioner Regulation Agency (**Ahpra**), the National Boards and legislators alike, there has never been a more important time to know your obligations before engaging in cosmetic medicine.

From 5 November 2026, the *Poisons and Therapeutic Goods Act and Regulation 2008* will be replaced by the:

- *Medicines, Poisons and Therapeutic Goods Act* 2022
- *Medicines, Poisons and Therapeutic Goods Regulation* 2026 (the **new Regulation**)

Part 9 of the new Regulation sets out requirements applicable to cosmetic medicine, adding clear expectations applicable to those prescribing and administering cosmetic use substances, particularly in relation to record-keeping and prescribing directions.

The new Regulation also imposes obligations on cosmetic medicine businesses, including in relation to storage, having risk management policies and procedures in place, and having emergency equipment available, amongst other obligations.

Medical practitioners and nurse practitioners prescribing cosmetic use substances must be satisfied the substances are approved. They must have personally reviewed the patient in person or by audiovisual link before giving a direction for the administration.

There must also be a written record of the direction, whether that is made by the prescriber or the nurse to whom the prescriber has given an oral direction, which may only occur if the prescriber is physically present during administration.

Nurses administering cosmetic use substances must make detailed written records in relation to administration, including but not limited to:

- the nurse's name
- the date of administration
- the batch number of the substance
- the patient and prescriber details
- the date on which the prescriber personally reviewed the patient, and
- the number of times and the intervals at which, the substance may be administered.

Breach of certain requirements will constitute an offence attracting serious penalties.

These changes come in addition to new Guidelines introduced by Ahpra and the National Boards in September 2025 (*Guidelines for registered health practitioners who perform non-surgical cosmetic procedures*) which introduced requirements in relation to training and education obligations on practitioners wanting to expand their scope of practice into non-surgical cosmetic procedures, amongst other requirements.

The increased scrutiny and regulatory measures have been prompted by a series of concerning complaints and patient outcomes, which have put a spotlight on practices within the industry.

Of particular concern to Regulators has been practises that they say put 'profit before patients'. Disciplinary action has been taken against businesses obtaining and distributing cosmetic use substances unlawfully, and non-registered practitioners and inexperienced nurses administering cosmetic use substances. For example, in January 2026 a Queensland nurse was banned from nursing for two years after injecting a formulation of botulinum toxin into a patient without consulting a doctor or obtaining a prescription, amongst other unsatisfactory conduct.

The new legislative framework imposes practical requirements on those practising cosmetic medicine, and now is the time to ensure compliance to avoid harsh penalties.

The fragile state of health data

Authors: Jehan Mata (Partner), Dinah Amrad (Associate) and Kaylee Nguyen (Paralegal)

While the digitalisation of health data enhances efficiency, the permanent nature of stolen medical records becomes a high-value target for identity theft and extortion. As healthcare data remains a primary target for cybercriminals, breaches now pose critical threats to patient safety, privacy, and operational continuity. Recent examples detailed below, demonstrate the scale of the risk and highlight that healthcare organisations of all sizes can be attractive targets because of the volume and sensitivity of the information they hold.

- **MediSecure:** approximately 12.9 million individuals may have had personal and health information relating to prescriptions exposed.
- **Medibank:** the cyberattack resulted in the theft and publication of sensitive customer information and has led to significant legal consequences. This was discussed in greater detail in the previous edition of our Sparke Bytes publication (which can be viewed here).
- **Genea Fertility:** sensitive patient information was compromised following a cyberattack.
- **Australian Clinical Labs:** more than 223,000 patients were affected, with personal, health and financial information compromised, and some information published on the dark web.
- **Partnered Health:** a recent cyberattack affected 21 clinics across Australia, with medical records and personal information stolen.

Known consequences

Cyber breaches in healthcare lead to significant regulatory penalties under the Notifiable Data Breaches scheme; organisations must notify affected individuals and the Office of the Australian Information Commissioner where an eligible data breach is likely to cause serious harm and the risk cannot be addressed through remedial action. For instance, with reference to the Australian Clinical Labs breach above, in a landmark privacy decision, Australian Clinical Labs received a $5.8 million civil penalty and a $400,000 legal cost order. The penalty stemmed from security deficiencies and reporting delays after a cyberattack compromised the data of over 223,000 individuals at Medlab Pathology. This was discussed in greater detail in the previous edition of this publication, which can be viewed here.

The consequences of a breach, also increase the likelihood of litigated complaints, investigations and class actions as patients may suffer distress and lose trust in the organisation. The Medibank cyber incident demonstrates how a cyberattack can develop into significant and ongoing legal exposure. This was discussed in greater detail in the previous edition of our Sparke Bytes publication, which can be viewed here.

Takeaways for healthcare providers

As a precautionary measure, healthcare providers must treat patient information as a high-value asset and recognise that protecting it is an important part of patient care; providers should undertake the following familiar steps:

- keep software and systems up to date and prevent the installation of unapproved software
- regularly back up important data
- provide ongoing staff training on phishing emails, fraudulent texts and suspicious calls
- maintain and regularly review a cyber incident response plan, and
- invest in appropriate cybersecurity measures, including antivirus software, secure access controls and multi-factor authentication. In the current environment, cybersecurity should not be treated as a one-off IT investment and should form part of an organisation's broader risk management and patient safety framework.

Takeaways for insurers / underwriters

Cyber claims involving healthcare providers - which appear to be on the rise - can be particularly complex because a single incident may create several types of exposure at once given a significant breach may result in regulatory investigations, class actions, legal costs, forensic investigation expenses, notification costs, business interruption, remediation costs and reputational damage.

Insurers should therefore consider not only the immediate costs of responding to a cyberattack, but also the potential long-term legal and regulatory exposure. This includes considering the type and volume of information compromised, the number of affected individuals, the insured's cybersecurity controls and whether third-party service providers may have contributed to the breach.

As for underwriters, when insuring healthcare organisations after a data attack, underwriters must enforce stricter risk evaluations, revise policy terms, and ensure full regulatory compliance. Before a health data attack occurs, cyber insurance underwriters should proactively check technical defences, assess third-party vendor risks, and require strict recovery tests.

To conclude, as healthcare becomes increasingly digital and interconnected, cyber risk will continue to evolve. For healthcare providers and insurers alike, protecting patient information is becoming an essential part of managing regulatory risk, organisational resilience and patient trust.

Snapshot: Law reform – improving accessibility to medication for those in rural and remote areas

Authors: Marie-Clare Elder (Partner) and Zara Smith (Law Graduate)

A historical piece of legislation was passed on 2 July 2026 changing the landscape of healthcare to improve accessibility to medication for those in rural and remote areas. The *Health Legislation Amendment (Prescribing of Pharmaceutical Benefits) Bill* 2025 will amend the *National Health Act* 1953 to permit authorised nurses to prescribe Pharmaceutical Benefits Scheme (**PBS**) medicines to patients, in collaboration with an authorised health practitioner. The changes follow the approval by all federal and state health ministers who unanimously concurred in December 2024 to promote a new national registration standard for 'designated registered nurse prescribers.'

This reform is a stepping stone in strengthening Medicare and the healthcare system, as recommended by the Scope of Practice Review Final Report, which was published in October 2024 and analysed '*the barriers and incentives health professionals face working to their full scope of practice in primary care*'.

From 1 October 2026, changes to the PBS administrative system will enable registered nurses who have completed the studies required by the Nursing and Midwifery Board of Australia to participate in the new prescribing arrangements permitted under the amended Act.

Federal Secretary Annie Butler commented that this reform will '*significantly improve access to equitable, timely and high-quality care*.' In addition, the Hon Mark Butler MP stated that this legislation change would broaden '*the scope of practice for suitably qualified nurses and make it much easier for people in many rural and remote communities to get the medicines they need*' and will provide '*greater opportunities for nurses to contribute to multidisciplinary team-based care*'. Importantly, the legislative changes to the *National Health Act* will ensure that PBS medication will be accessible to persons who are unable to attend a doctor, removing the barriers to access for patients seeking medical assistance.



Navigating the TGA's new guidance on advertisements of prescription medicines

Authors: Kerri Thomas (Partner) and Dinah Amrad (Associate)

On 18 June 2026, the Therapeutic Goods Administration (**TGA**) published its new guidelines on advertising restrictions for prescription medicines. In summary, the *Therapeutic Goods Act* 1989 (the **Act**) prohibits advertising prescription medicines, except in very limited circumstances. This is because the use of prescription medicines may carry specific risks and decisions about their use should therefore be made by patients in consultation with an appropriately qualified health practitioner and not encouraged or influenced by advertising.

What the TGA has said

Helpfully, the TGA has provided some examples of what will be prohibited advertisements relating to prescription medicine/s:

- References to prescription medicines through a business name or logo.
- Promotion of health services that supply or prescribe prescription medicines.
- Promotion of prescription medicines for the treatment of specific health conditions by way of a statement, pictorial representation or design using specific prescription medicines to treat specific medical conditions.
- Direct mass marketing campaigns delivered at public events (such as webinars or seminars).
- References to third-party information.
- Testimonials and endorsements.
- Content within the social media platforms created or managed by practitioners or social media influencers with whom they have collaborated.

There are, however, some exceptions and advertising is permitted if it:

- is specifically targeted to health professionals – i.e. medical practitioners, nurses, purchasing officers, practice managers and other persons mentioned in s 42AA of the Act
- is provided in a confidential context by a health practitioner directly to a patient in the course of treating that patient
- is authorised or required by a government or government authority within Australia i.e. for the purposes of public health campaigns conducted, approved or funded by Commonwealth, state, territory or local governments
- is considered permissible and has been granted approval. An example provided by the TGA is public health campaigns promoting the use of prescription medicines that are likely to refer to serious forms of disease (for example, vaccine preventable diseases), and
- refers to the publication of price lists in compliance with the Code i.e. price information for some prescription medicines is permissible, if certain conditions are met.

Consequences of non-compliance

Failure to comply with the TGA's guidelines may lead to an investigation undertaken by the TGA. Actions will be taken based on the level of risk to public health and safety, varying from education and warnings to fines and legal action and will include:

- Suspensions
- Cancellations
- Advertising directions and prevention notices
- Regulatory decisions and notices
- Compliance undertakings
- Infringement notices in the form of financial penalties in response to certain breaches of the Act
- Court proceedings against the offender by way of criminal prosecutions in association with the Commonwealth Director of Public Prosecutions. It is the TGA's practice to publish details of regulatory compliance decisions and actions on its website.

Key takeaways

Business owners

To prevent being investigated by the TGA, business owners ought to first familiarise themselves with the new guidelines and proactively commence a review of all their advertising content appearing on their websites and social media platforms to ensure that all advertisements remain compliant with the new guidelines. Delegating the review to a website designer/social media manager does not absolve the business owner from their responsibility in maintaining that all advertisements remain compliant to the guidelines.

Insurers and underwriters

Insurers should consider the consequences of responding to TGA's investigations; if the TGA determines that the compliance risk is high, it may lead to long and drawn prosecutions which potentially attract fines and penalties.

Consideration need to be given to how to work with and support insureds take the appropriate risk management and auditing of their advertising to avoid claims of this nature – which can end up being very expensive- being made on policies.



Snapshot: Changes in Queensland: Health Legislation Amendment Bill 2026

Authors: Mark Sainsbury (Partner) and Grace Garraway (Law Graduate)

The *Health Legislation Amendment Bill 2026* (the **Bill**) was introduced to the Queensland Parliament on 4 June 2026. The purpose of the Bill is to amend a number of health portfolio Acts, including reforms to Queensland's mental health framework, public health reporting requirements, health infrastructure acquisition powers, pharmacy ownership arrangements and tobacco enforcement measures.

The Bill passed Parliament without amendment on 27 August 2026 and received Royal Assent on 3 September 2026, becoming the *Health Legislation Amendment Act* 2026 (the **Act**).

The Act amends the following existing pieces of legislation:

Mental Health Act 2016

The amendments introduce a range of reforms relating to psychiatric examinations, forensic orders and the operation of authorised mental health services, including:

- introducing a new power permitting the detention of a person for 24 hours, extendable up to 72 hours in certain circumstances, while a psychiatrist report is being prepared on the Chief Psychiatrist's initiative
- transfer of responsibility for reviewing forensic orders (Criminal Code) from the Mental Health Review Tribunal to the Mental Health Court, and
- creating a new framework for managing patients subject to forensic orders or treatment support orders who are deported, removed, extradited or taken into immigration detention.

Unlike the other amendments that have already passed, the above amendments will commence on a date to be fixed by proclamation.

Hospital and Health Boards Act 2011

The amendments enable Queensland Health to compulsorily acquire land for a health infrastructure purpose.

Pharmacy Business Ownership Act 2024

The amendments restrict affiliations between pharmacy businesses and supermarket businesses in the online environment.

Public Health Act 2005 and *Public Health Regulation 2018*

The amendments expand information-sharing for school immunisation programs and introduce more targeted notifiable condition reporting requirements, including more granular reporting requirements for pathology request notifiable conditions, with hepatitis C now prescribed for RNA testing only to assist public health surveillance of active infections.

Tobacco and Other Smoking Products Act 1998

The amendments alter the forfeiture process for illicit tobacco and other nicotine products.

What happens when medical devices go wrong? Medical devices in the media and a new era of litigation

Authors: Kerri Thomas (Partner) and Sophie Sneyd (Law Graduate)

Australia's Therapeutic Goods Association (**TGA**) has been the subject of a great deal of media attention in recent months following allegations that it has fallen short in monitoring the regulations around medical device defects.

Media attention

Pain pumps

On 18 July 2026, the Sydney Morning Herald published Vicki Kelly's story.[1] Ms Kelly was a recipient of Medtronic's SynchroMed II intrathecal pump, a programmable and implantable medical pump that dispenses opioids via a catheter to deliver pain relief. She later suffered a blood clot which blocked an artery in her spinal cord. She spent 17 months in hospital and is now a paraplegic.

According to the Australian Institute of Health and Welfare, up to 150,000 Australians have experienced medical device incidents requiring hospitalisation annually.

This particular pump was subject to seven Class I hazard alerts by the TGA since 2013. A Class I hazard alert is issued where there is a 'reasonable possibility of serious injury or death'. The pumps were recalled in 2008, sale of the pump was then banned by US regulators in 2015, although the ban was lifted in 2017 after design changes were made to the device. However, this information was never communicated to Ms Kelly.

Portable defibrillators

On 19 July 2026, the Sydney Morning Herald also published a story about Rapid Response Revival, the manufacturer of the CellAED, a portable defibrillator, which recently entered voluntary administration after a spate of reports that the device was failing to provide shocks to patients based on their cardiac rhythm.[2] Reports included instances of the device providing unprompted or unprogrammed shocks. CellAED was approved by the TGA in 2021 without human clinical evidence showing it could save a life. It was pulled from UK market in around 2024 due to concerns of a lack of clinical evidence to back the device.

While the TGA was aware of the concerns raised in the UK, it was not until February this year that the licence for sale in Australia was cancelled. Since 2023, the TGA had received six reports where the patient died after the device failed to provide a shock to a person having a heart attack.

Spinal cord stimulators

An opinion piece by researchers from the University of Sydney and UNSW in April 2025 reported that surgically implanted spinal cord stimulators resulted in a quarter of recipients requiring corrective surgery, usually within the first three years.[3] The device operates by sending electrical pulses to the spinal cord to disrupt pain signals travelling to the brain. Dr Caitlin Jones noted that the cost to the insurer for patients trialling the device was around $14,000.[4] For patients looking for a more permanent implantation, the cost to the insurer became around $55,000, with outliers found to have cost over $500,000.

Concerns are mounting particularly after a 2024 ABC Four Corners episode found that 79% of adverse events were considered 'severe' and 13% considered 'life threatening'.

Blood-cooling devices

The Sydney Morning Herald shed light on another medical device defect story in August, this time on a machine used during routine heart surgeries.[5] A design flaw in the 3T Heater-Cooler water tanks, a device used to maintain patient temperature during heart surgery, led to growth of mycobacterium chimaera. The bacteria then came into contact with the patient's blood as it passed through the machine or sprayed a fine mist into the patient's open chest. Twenty five per cent of Australia's 3T devices were infected with the bacteria.

Fay Sherret underwent a heart valve replacement surgery and later died after the bacteria-infected device was used during her operation. The Sydney Morning Herald found that three other patients had died from infections linked to the machines between 2016 and 2022. The TGA had received 22 reports between 2021-2025 about the contaminated devices.

These devices are still in use after design fixes were made. Disinfection protocols were issued by the TGA, but this particular bacteria is difficult to eradicate and NSW authorities again found an infected device last year.

Litigation trends

Pelvic mesh litigation

The recent and highly publicised series of class action lawsuits against various manufacturers and suppliers of pelvic mesh and sling implants also looms large.

Shine Lawyers commenced class actions against Ethicon and Johnson & Johnson in 2012, US-based Astora in 2018, and Boston Scientific in 2021. The claims were similar across the three class actions, primarily alleging that the pelvic mesh devices manufactured and supplied to Australian women were defective, resulting in serious complications including chronic pain, infection, organ perforation and other long-term health issues.

The 2012 action settled in 2023 for AUD$300 million.[6] The Federal Court of Australia placed a stay on the 2018 action after Astora filed for bankruptcy in the US.[7] The implants subject of this action were never recalled in Australia but were taken off the Australian market. The 2021 action settled for AUD$105 million.[8]

Contraceptive devices

Patrice Turner commenced Supreme Court proceedings against Bayer alleging that its implantable permanent contraceptive device, Essure, caused localised inflammatory foreign body responses in the fallopian tubes.[9] Ms Turner alleged that the device was defective and that it was known that in some cases, the device would corrode, migrate, break, or perforate the surrounding tissue. In this case, the Court ultimately found in favour of Bayer noting that Ms Turner had not provided enough evidence to support her allegations.

The cost for insurers

Currently, there is not yet enough publicly available data yet to estimate the ongoing costs to insurers when it comes to medical device defects.

However, with increased visibility of defective devices in the media and the general rise of class actions, the likelihood of more claims for losses associated with these medical devices seems inevitable.

[1] Liam Mannix, Henrietta Cook, Clay Lucas and Amelia Ballinger, 'Race to the Bottom': Investigation reveals toll of weak medical device laws', *The Sydney Morning Herald* (onling, 18 July 2026) <Injuries from medical devices Australia: Woman's SynchroMed II back pain pump leaves her paralysed as investigation reveals TGA approval anomalies>

[2] Henrietta Cook and Liam Mannix, 'Sparking, burning and a 50-second delay: The deadly loophole in Australia's medical device rules', *The Sydney Morning Herald* (online, 19 July 2026) <CellAED medical device failure: Defibrillators banned in UK approved by TGA as device approvals come under scrutiny>

[3] Ian Harris, Adrian C Traeger and Caitlin Jones, 'Evidence doesn't support spinal cord stimulators for chronic back pain – and they could cause harm', *The Conversation* (online, 10 April 2024) <Evidence doesn't support spinal cord stimulators for chronic back pain – and they could cause harm>

[4] Cailin Jones et al, 'Spinal cord stimulation patterns of care, re-interventions, and costs for private health insurers, Australia, 2011-22: a retrospective observational study' (2025) 223(5) *Medical Journal of Australia* 243

[5] Liam Mannix and Henritta Cook, 'Fiona's mum died after a heart surgery machine gave her a fatal infection. Hospitals are still using it', *The Sydney Morning Herald* (online, 1 August 2026) <3T Heater-Cooler medical device failure: Heart surgery machines lead to fatal infections, but Australian hospitals still use many devices>

[6] Angela Wood and Jemima Stratton, 'Settlement approval for pelvic mesh class action against Johnson & Johnson and Ethicon', *Maddocks* (Online Insights, 23 May 2023) <Maddocks | Settlement approval for pelvic mesh class action against...>

[7] 'Astora Mesh Class Action', *Shine Lawyers* (Web Page) <American Medical Systems Mesh Class Action | Shine Lawyers>

[8] 'Settlement reached in Boston Scientific mesh class action', *Shine Lawyers* (Media Release, 20 January 2022) <Settlement Reached In Boston Scientific Mesh Class Action | Shine Lawyers>

[9] *Patrice Sarah Turner v Bayer Australia Ltd* (ACN 000 138 714) [2024] VSC 760

The development of psychological and nervous shock claims: genuine harm or growing exposure?

Authors: Mark Doepel (Partner) and John Youssef (Associate)

In recent years, the insurance market has seen an increase in claims for psychological injury and nervous shock, which insurers and regulators have identified to be a significant driver of rising insurance premiums, increased claims excesses and deductibles, and a tightening in insurer capacity, coverage availability, and risk appetite.

As reported in the Financial Review in June 2025, '*Mental health claims grew from $1.2 billion in 2019 to $2.2 billion in 2024, with stress, anxiety, depression, burnout and bullying at work among the leading reasons claimants give for being unable to return to the workforce*.'[1] These affordability pressures have renewed the calls for reform in this area of civil liability.

The legislative framework governing claims for mental harm can be found in the *Civil Liability Act 2002* (NSW) (**CLA**), Part 3 (ss 27-33), which includes pure mental harm (absent a psychical injury) and consequential mental harm (which is a consequence of a physical injury). To bring a claim for pure mental harm arising from shock as a secondary victim, it requires a recognised psychiatric illness (i.e., it must go beyond mere grief or anxiety, such as Post-Traumatic Stress Disorder), and being a close family member of the victim or having witnessed the incident or its immediate aftermath.

Importantly, the success of a nervous shock claim does not depend on the primary victim's claim to be successful. The claims are separate and distinct: *Amanda Biggs v Garry Raymond O'Connor* [2021] VSC 826 [79].

For example, a parent who acts as tutor for a primary victim may also bring a nervous shock claim, which has the effect of widening the potential scope of liability arising from a single incident.

The Insurance Council of Australia (**ICA**), in its October 2025 report of *Sustainable Public Liability Insurance Market in Australia: The Case for Civil Liability Reform*, noted the increase of claims involving psychological injury, which are becoming increasingly common and costly.[2] This is supported by data from Safe Work Australia, which indicated that psychological injury claims can cost up to four times more than physical injury claims alone.

Mr Andrew Hall, Executive Director and CEO of ICA, noted that '*Insurers have been working with businesses facing affordability pressures and challenges accessing insurance, but it is clear improvements to civil liability settings are needed to ensure they remain fit for purpose.*' Further, that '*After nearly 25 years, it is the appropriate time to review civil liability laws to ensure public liability insurance is on a sustainable footing and continues to provide the security businesses rely on*.'

To address the impact of psychological claims on insurance, ICA has made several reform recommendations for policymakers. For example, in a common law claim that involves both physical and psychological injury, damages should be based on whichever injury is more serious, not a combination of both. Further, that a disputed psychological whole person impairment should be determined by a court appointed independent expert, and limiting consideration of psychological injury claims to cases where treatment was sought within 12 months of the initial physical injury.

Regarding third-party nervous shock claims, the ICA has recommended imposing additional thresholds, such as requiring some claimants to have been present at or to have directly witnessed the incident. These concerns arise from cases such as the death of an elderly hospital patient, where claims were brought by an extensive group of relatives (including the children and their spouses, and their grandchildren) despite none having sought medical treatment and the alleged diagnoses relying solely on uncorroborated psychiatric reports. The cost of defending these claims was so significant that settlement was reached to avoid excessive legal and expert expenses.

While psychological injury and nervous shock claims are increasing, it is important to recognise that these reform discussions are not aimed at reviving scepticism toward mental harm, but at introducing appropriate safeguards and boundaries to ensure claims are properly assessed and fairly applied. Judicial recognition that psychiatric injury constitutes a real and compensable form of harm was reinforced in *Tame v New South Wales* (2002) 211 CLR 31 [236], where Gummow and Kirby JJ at [236] observed that negligence principles must be applied without '*artificial constrictions*' merely because the injury is psychiatric.

In *Sorbello v South Western Sydney Local Health Network; Sultan v South Western Sydney Local Health Network* [2016] NSWSC 863, two Court accepted two parents developed distinct psychiatric injury after being exposed to the same traumatic event of their son suffering from severe injury as the result of oxygen deprivation during his birth at Bankstown Hospital.

The Court accepted the mother had Persistent Depressive Disorder, accompanied by anxiety symptoms, from being the primary carer of her significantly disabled son, while the father exhibited emotional withdrawal and avoidance behaviours, leading to his separation from the family. The mother and father had been awarded, among other heads of damages, $208,000 and $21,000, respectively, for non-economic loss. Unlike the mother, the father's working capacity was not found to have been causally linked to the psychiatric injury, and he would therefore be required to return to full-time capacity in 12 months.

The case demonstrated that psychiatric injury may manifest in different ways, each requiring careful, evidence based assessment, while reinforcing the need for reform that does not undermine genuine claims. The increasing prevalence and cost of psychological injury and nervous shock claims highlight the tension between ensuring fair compensation for genuine psychiatric harm and maintaining a sustainable liability insurance system. While the current legislative framework recognises mental harm as a compensable injury, the increasing scope and frequency of these claims has prompted renewed scrutiny from insurers, regulators, and policymakers, making this an area of civil liability law that may continue to evolve.

[1] https://www.afr.com/policy/economy/rise-in-mental-health-claims-a-symptom-of-a-bigger-malaise-20250709-p5mdnf

[2] https://insurancecouncil.com.au/wp-content/uploads/2026/03/20260306-Public-Liability-submission-ICA.pdf



Health practitioner register updated under landmark reforms

Authors: Marie-Clare Elder (Partner) and Lani Carter (Special Counsel)

In April 2026 it was announced that changes to the National Law would allow the Ahpra to publish sexual misconduct findings on the publicly available register of practitioners.

The register will now include Tribunal decisions dating back to July 2010 where the practitioner was found to have been involved in sexual misconduct which resulted in a finding of professional misconduct.

Most tribunal decisions are already published online, with a link included on the public register. Under the changes, the register entry will now clearly state when the decision involved sexual misconduct.

Sexual misconduct covers various behaviours inside and outside of a practice setting, including professional boundary violations, sexual harassment and criminal offences.

Changes published as part of the first phase resulted in 107 health practitioners having existing sexual misconduct findings added to the register, including 86 noted as no longer practising.

CEO Justin Untersteiner commented that these findings empower patients to make informed choices about their care and reinforces that breaches of trust will not be hidden.

'*For individuals who have been the subject of a sexual misconduct finding, but who are not currently registered, the National Law changes also impose new, nationally consistent requirements in the event they seek to regain registration*.'

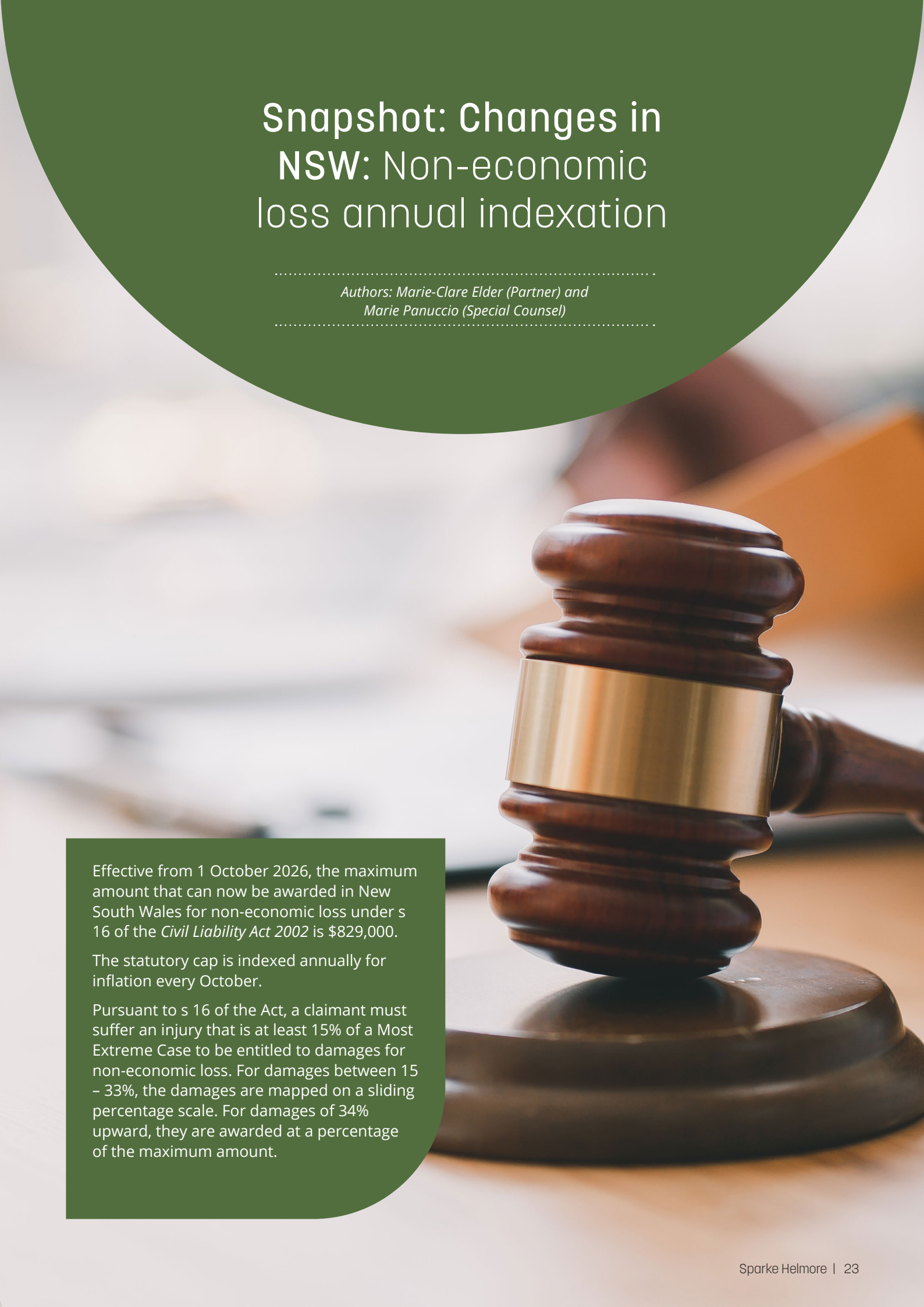
Publication of sexual misconduct findings will have obvious effects on a practitioner's career and employment prospects.

Practitioners should contact their professional indemnity insurer immediately upon receipt of any complaint suggesting misconduct of a sexual nature to ensure that they are properly advised and represented throughout the show-cause process.



Snapshot: Changes in NSW: Non-economic loss annual indexation

Authors: Marie-Clare Elder (Partner) and Marie Panuccio (Special Counsel)



Effective from 1 October 2026, the maximum amount that can now be awarded in New South Wales for non-economic loss under s 16 of the *Civil Liability Act 2002* is $829,000.

The statutory cap is indexed annually for inflation every October.

Pursuant to s 16 of the Act, a claimant must suffer an injury that is at least 15% of a Most Extreme Case to be entitled to damages for non-economic loss. For damages between 15 – 33%, the damages are mapped on a sliding percentage scale. For damages of 34% upward, they are awarded at a percentage of the maximum amount.

Our health team

NSW / ACT



Marie-Clare Elder
Partner, Health Team Leader
+61 2 9260 2491 | +61 481 388 259
Marie-Clare.Elder@sparke.com.au



Marie Panuccio
Special Counsel
+61 2 9260 2483 | +61 415 801 991
Marie.Panuccio@sparke.com.au

VIC / TAS



Kerri Thomas
Partner
+61 3 9291 2305 | +61 410 505 217
Kerri.Thomas@sparke.com.au



Sophie Pennington
Partner
+61 3 9291 2382
Sophie.Pennington@sparke.com.au



Jehan Mata
Partner
+61 3 9291 2374 | +61 403 373 159
Jehan.Mata@sparke.com.au

QLD



Mark Sainsbury
Partner
+61 7 3016 5033 | +61 408 687 770
Mark.Sainsbury@sparke.com.au

SA / NT



Lauren McHugh
Partner
+61 8 8415 9830 | +61 409 113 506
Lauren.McHugh@sparke.com.au



Lani Carter
Special Counsel
+61 8 8415 9836 | +61 414 744 735
Lani.Carter@sparke.com.au

WA



Aimee Dash
Partner
+61 8 9288 8003 | +61 473 738 084
Aimee.Dash@sparke.com.au

Contributors



Mark Doepel
Partner
+61 2 9260 2445 | +61 402 000 920
Mark.Doepel@sparke.com.au



Jason Kwan
Partner
+61 3 9291 2376 | +61 487 003 033
Jason.Kwan@sparke.com.au



Kate Hodgkinson
Senior Associate
+61 2 9260 2771
Kate.Hodgkinson@sparke.com.au



Dinah Amrad
Associate
+61 3 9291 2212
Dinah.Amrad@sparke.com.au



John Youssef
Associate
+61 2 9260 2501
John.Youssef@sparke.com.au



Grace Garraway
Law Graduate
+61 7 3016 5112
Grace.Garraway@sparke.com.au



Sophie Sneyd
Law Graduate
+61 3 9291 2284
Sophie.Sneyd@sparke.com.au



Zara Smith
Law Graduate
+61 2 9260 2548
Zara.Smith@sparke.com.au



Kaylee Nguyen
Paralegal
+61 3 9291 2240
Kaylee.Nguyen@sparke.com.au

Sparke•Helmore

www.sparke.com.au

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