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Product Liability Update

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Welcome to W+K's Product Liability Update

Issue 1, December 2022

Product Liability is an area facing ongoing regulatory scrutiny, and new product risks and exposures. In this regular publication, we will provide regulatory updates, summaries of significant cases and commentary on other industry-specific issues.

In this issue, we look at the ACCC's focus on safety issues affecting young children, recent case highlights from Australia and New Zealand, and insights into product safety news in the medical/pharmaceutical and manufacturing sectors.

We will continue to bring you further updates and new developments as they arise. If you would like to discuss any of the articles in this update, please contact W+K's Product Liability + Recall team.

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Regulatory updates

In June this year, the ACCC announced its product safety priorities for 2022/23, with one key focus being safety issues affecting young children.[1]

Safety issues affecting young children

The ACCC is focusing on consumer product safety issues for young children, including compliance, enforcement and education initiatives. It is addressing high-risk safety issues in consumer products for young children, such as small high-powered magnets, baby dummies and dummy chains, sleep aids and toys for children under three, by:

- taking appropriate regulatory and enforcement action
- developing communication and education strategies to empower carers to make decisions and take actions that protect young children's interests and safety, and
- working with suppliers to improve recall effectiveness of young children's products.[2]

In August 2022, the ACCC launched a dedicated website, *Your First Steps*, to provide parents and carers with the latest, most reliable information on unsafe products and best practices to keep their baby safe.

Data over the last 20 years shows that around three infant deaths occur each year associated with inclined sleep products and other infant sleep aids. The *Your First Steps* website covers new and emerging product categories to help parents know what to look for when selecting and using baby products. It also provides important information about commonly used baby products that can be dangerous.[3]

There have also been several recalls this year in this category, largely related to choking hazards, including items such as teething toys, products containing button batteries, infant rattle products and soft toys. Notably, these recalls have extended to global online marketplaces such as Etsy.

Infant sleep products

Implementing strategies to prevent injuries and deaths to infants caused by inclined products that can be used for sleep is an ACCC Product Safety Priority for 2022-23.[4] In August, the ACCC published a range of proposed regulatory options to achieve this. It also questioned whether the existing mandatory safety standards for folding cots and household cots require updating.

An 'infant sleep product' is any product that has a surface on which an infant may lie that creates a sleep environment, including products that soothe or settle, such as baby hammocks, bassinets, bedside sleepers, household cots and folding cots.[5]

The existing standards are currently mandated by the government, with Australian Consumer Law regulators monitoring several mandatory safety standards relevant to infant products for compliance. Designers, manufacturers and suppliers need to ensure that products supplied into the Australian market comply with the safety requirements.

[1] https://www.productsafety.gov.au/news/accc-product-safety-priorities-announced-at-national-consumer-congress
[2] https://www.productsafety.gov.au/system/files/CPSD%20SPAR%20Product%20safety%20priorities%202022-23%20publication%20-%20final%20edit.pdf
[3] https://www.productsafety.gov.au/news/accc-launches-your-first-steps-to-help-parents-keep-their-baby-safe
[4] https://consultation.accc.gov.au/accc/infant-inclined-consultation-regulation-impact/supporting_documents/Infant%20Sleep%20Products%20Consultation%20Paper.pdf, page 8
[5] Some infant products that may fall within this category are already subject to mandatory standards, such as baby walkers, beanbags, prams, strollers, and car seats including capsules.

Following its July 2021 Issues Paper on risks associated with inclined sleep products and inclined non-sleep products, the ACCC procured two expert reports that confirmed curvature, rigidity and the materials used in some products pose a risk to infants. The reports indicated these factors, together with any incline, are worth considering. Currently, there are no Australian mandatory standards that address risks associated with incline curvature and materials used.

The ACCC will finalise strategies to prevent injuries and deaths caused by infant sleeping products by:

- consulting stakeholders on the costs and benefits of a range of potential policy options to prevent injuries and deaths caused by infant inclined products
- determining whether regulatory action should be recommended to the Minister, including whether it is appropriate to recommend a safety standard be implemented under the Australian Consumer Law (ACL), and
- increasing education and awareness of the hazards associated with infant inclined products.[6]

Toppling furniture

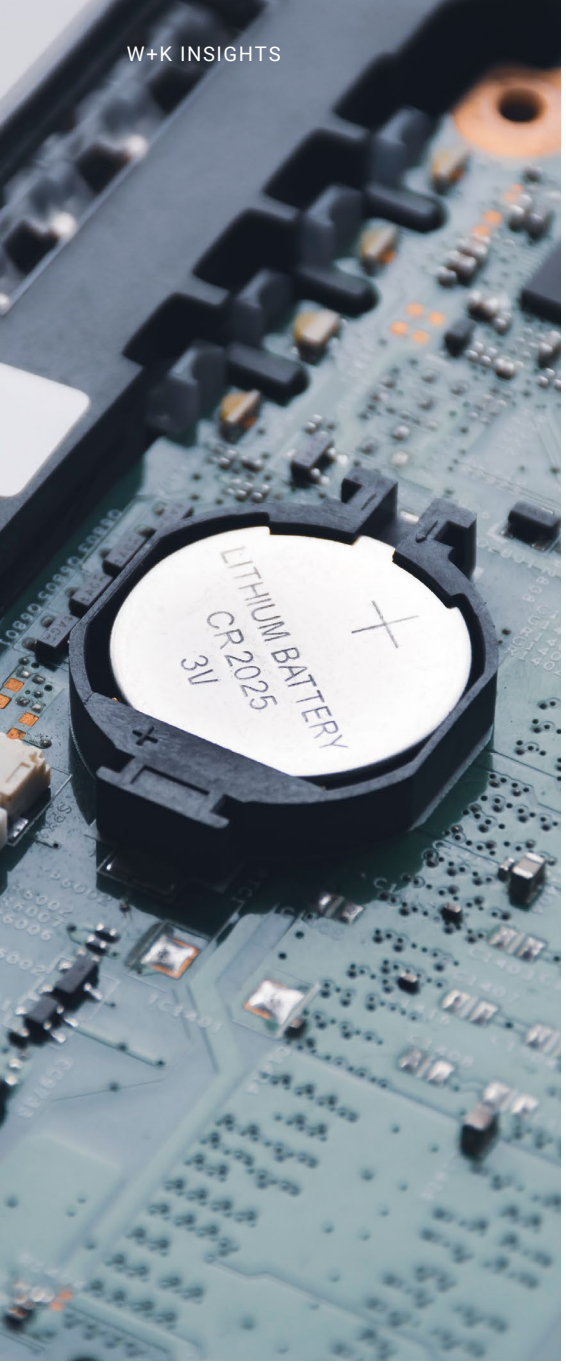
Free standing furniture and TVs can become a safety risk if they become unstable and tip over. Toppling furniture has resulted in at least 28 deaths in Australia since 2000 and continues to cause close to 20 injuries every week. Children under the age of five are most at risk of serious harm and suffer the highest proportion of deaths and injuries in Australia. Adults over the age of 60 are also represented in Australian fatality data. All age groups are at risk of injury, although children are disproportionately represented.[7]

The most common furniture involved in accidents includes chests of drawers, wardrobes, bookcases, cabinets and entertainment units. Injuries include cuts, open wounds, broken bones, brain injury and amputation. Death typically arises due to the weight of the item striking the individual.[8] Anchoring kits, which are supplied with some furniture and televisions or are available for purchase separately, can be used to attach furniture to a wall or other secure surface. Anchoring kits are typically effective when used correctly but they are not always used by consumers.

The safety risk is due to a combination of design factors, and consumer behaviours and awareness. The ACCC is currently proposing regulatory options aimed at improving product design and increasing wall-fitted anchoring and consumer education. The ACCC will finalise strategies to improve the safety of toppling furniture by:

- consulting stakeholders on the costs and benefits of a range of potential policy options to prevent injuries and deaths caused by toppling furniture
- determining whether regulatory action should be recommended to the Minister, including whether it is appropriate to recommend a safety standard be implemented under the ACL, and
- increasing education and awareness of the safety hazards associated with toppling furniture.

[6] https://www.productsafety.gov.au/system/files/CPSD%20SPAR%20Product%20safety%20priorities%202022-23%20publication%20-%20final%20edit.pdf
[7] https://www.productsafety.gov.au/system/files/Toppling%20furniture%20and%20televisions%20-%20issues%20paper.pdf
[8] https://www.accc.gov.au/media-release/accc-seeking-to-reduce-toppling-furniture-dangers



There is currently no mandatory safety standard or information standard specifically relating to toppling furniture in Australia. A range of voluntary measures have sought to address the safety risks, including:

- a voluntary standard for free-standing furniture published by Standards Australia
- other voluntary standards relevant to toppling televisions
- voluntary recalls, and
- a range of product safety initiatives undertaken by governments, industry, and advocacy groups to improve safety outcomes (includes initiatives to address the combination of design, anchoring, consumer behaviour and awareness factors).

Recent product recalls notably include lofts and bunk beds from Amart, chests of drawers, bookcases and cabinets from IKEA, and various dining chairs.

“There is currently no mandatory safety standard or information standard specifically relating to toppling furniture in Australia. A range of voluntary measures have sought to address the safety risks.

Lithium-ion batteries

The ACCC is scoping lithium-ion battery safety issues and identifying potential hazard prevention strategies by:

- conducting a short study to scope potential consumer product safety hazards associated with lithium-ion batteries
- engaging with relevant stakeholders, including state and territory electrical regulators to assess potential risk controls, and
- proposing risk mitigation strategies (if required), including potential improvements to the current regulatory framework.

New therapeutic products regulatory regime in NZ

The New Zealand Government is currently developing a new therapeutic products regulatory regime to replace the existing Medicines Act 1981. The Therapeutic Products Bill is due to be introduced to Parliament at the end of 2022.

The purpose of the Bill is to provide for acceptable safety, quality and efficacy of medicines, medical devices and natural health products. The Ministry of Health Therapeutics Policy Team recently reported the Bill has almost doubled in size due to feedback on the exposure draft in 2018, health system reforms, lessons from COVID-19, and regulation of natural health products (NHPs) made from natural ingredients or synthetic equivalents, such as synthetic vitamins and herbal remedies.

NHPs are currently regulated through various legislation depending on the type of product (e.g. dietary supplements under the Dietary Supplements Regulations 1985, and beauty products under the Hazardous Substances and New Organisms Act 2017). The intent is that having a single Bill and specific NHP regulatory regime will help clarify the nature of interfaces with other therapeutic products in the Bill and other pieces of legislation.

The Bill will regulate activities across a therapeutic product's lifecycle, including product development, pre-market activities (e.g. clinical trials and manufacturing) and authorisation for import, supply or export. Consistent with international practice, the product sponsor will also have special 'post-market regulation' responsibilities, such as implementing a surveillance system and carrying out preventative and corrective actions (at their own initiative or in response to regulator direction).

Biologics have not been previously regulated through a consistent approach. Under the Bill, biologics (e.g. products containing cells and tissues) and genomic medicine products (e.g. gene therapies) may be regulated as a medicine or medical device, depending on the mode of action (e.g. genetic testing kits used at home or in a clinical setting will likely be regulated as medical devices). The regulator will establish authorisation pathways in secondary legislation, which are tailored to product risk profiles and proposed uses.

Currently, regulatory approval is only needed for clinical trials of new medicines and not for new uses of already approved medicines. The new scheme aligns with OECD guidance and international Good Clinical Research Practice and will require individuals seeking to conduct a clinical trial on a medicine or medical device to obtain a licence or permit, in parallel with any ethics approval process.

Recent case highlights

First corporate penalty for failing to comply with a mandatory recall notice

***Australian Competition and Consumer Commission v Mercedes-Benz Australia/Pacific Pty Ltd* [2022] FCA 1059**

The Federal Court has ordered Mercedes-Benz Australia/Pacific Pty Ltd (Mercedes) to pay penalties of up to $12.5 million, and a contribution of $100,000, to the ACCC's costs for failing to use attention-capturing high-impact language when communicating with consumers about the compulsory recall of potentially deadly Takata airbags.[9]

Mercedes admitted that it had breached the ACL by failing to implement its communication and engagement plan for contacting consumers as required by the Takata Recall Notice when it communicated with some consumers about the Takata recall.

The Takata airbag recall is the world's largest automotive recall affecting an estimated 100 million vehicles globally. It is the most significant recall in Australian history, affecting over four million Takata airbags in around three million vehicles.

Defective Takata airbags have the potential to mis-deploy and send sharp metal fragments into the vehicle cabin. They have been associated with 33 deaths and over 350 injuries globally. In Australia, one person has died and another has been seriously injured in separate incidents caused by the mis-deployment of a Takata airbag.

The Takata Recall Notice required vehicle manufacturers to implement a communication and engagement plan for contacting consumers and to use appropriately urgent terms to maximise rates of replacements of Takata airbags.

Mercedes staff had described the recall as a "precaution" or said words to the effect that the type of airbags used in Mercedes vehicles had not caused any accidents, injuries or deaths in other manufacturers' vehicles. Those statements were not accurate and had the potential to give the impression to consumers that the airbag replacement was less urgent.

Under the Takata airbag recall, suppliers were required to recall and replace defective Takata airbags by 31 December 2020 and develop and implement a plan to communicate with consumers to maximise replacement of these airbags.

This is the first time a company has been penalised for failing to comply with a mandatory recall notice. This judgment sends a strong signal that companies must comply with their product safety obligations under the ACL.

[9] https://www.accc.gov.au/media-release/mercedes-to-pay-125m-for-failing-to-comply-with-takata-recall-communication-plan

Applicability of New Zealand consumer legislation to international manufacturers

***Body Corporate Number DPS 91535 v 3A Composites GmbH* [2022] NZHC 985**

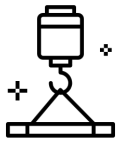
The High Court of New Zealand recently decided that the Consumer Guarantees Act 1993 (CGA) and Fair Trading Act 1986 (FTA) do not have extraterritorial jurisdiction. This decision confirms that the acts do not apply to overseas manufacturers that do not have a presence as a trading entity in New Zealand (NZ).

The case concerned proceedings served on a German manufacturer of a cladding product, 3A Composites GmbH (3AC). The plaintiffs alleged negligence and breach of the CGA and FTA for supplying an allegedly combustible product. 3AC protested the Court's jurisdiction. The Court accepted 3AC's protestations in part. While the Court had jurisdiction over the tortious claims, the CGA and FTA do not have extraterritorial reach.

Under the CGA, the only reference to extraterritorial reach is in the definition of "manufacturer", which includes an importer or distributer where the goods are manufactured outside NZ and the foreign manufacturer of the goods does not have an ordinary place of business in NZ. The Court considered the definition would have no utility if the CGA was intended to have extraterritorial reach because consumers would seek redress directly from the manufacturer rather than the importer. Therefore, the CGA was not intended to have extraterritorial effect.

The Court then considered the FTA. Section 3(1) extends the act to conduct by any person carrying on business in NZ. The Court found no evidence 3AC ever established itself as a NZ trading entity. Rather, 3AC had appointed the other defendants as its exclusive distributors. Therefore, it found 3AC sat outside the scope of the FTA.

In *obiter* comments, the Court found that if the decision on jurisdiction was wrong and the CGA did have extraterritorial reach, cladding was not a 'consumer good' for the purposes of the CGA. This was because it is ordinarily acquired by construction contractors / building companies for construction of residential and commercial premises, consistent with the definition of goods that excludes the whole or parts of whole buildings unless they are easily removeable structures not designed for residential accommodation.



Industry insights

Medical/pharmaceutical

The TGA is the medicine and therapeutic regulatory agency of the Australian Government. As part of the Department of Health, the TGA regulates the quality, supply and advertising of medicine, pathology devices, medical devices, blood products and most other therapeutics.

In July 2022, the TGA released its priority areas for compliance activities regarding the import, advertising and supply requirements of the *Therapeutic Goods Act 1989*.[10] These priorities are to:

- deter and address the unlawful import, advertising and supply of unapproved therapeutic goods associated with COVID-19
- disrupt and address the unlawful import, advertising and supply of nicotine vaping products
- ensure compliance with the requirements of the *Therapeutic Goods Act 1989* across the medical cannabis industry
- disrupt and address the unlawful import, manufacture, advertising and supply of unapproved performance and image-enhancing therapeutic goods, including sports supplements, with a focus on products containing schedule 4 and 8 poisons
- deter and address the unlawful import, advertising and supply of unapproved therapeutic goods used in the beauty and cosmetic dental industry
- address the unlawful use of restricted and prohibited representations in advertisements that have not been approved or permitted, particularly those that target especially vulnerable consumers, and
- deter and address the unlawful advertising of unapproved therapeutic goods on e-commerce platforms, including for pregnancy and prenatal goods, weight-loss products, and hangover cures.

Manufacturing

Mosaic Brands has paid $266,400 in penalties after the ACCC issued two infringement notices regarding alleged false or misleading representations made by Mosaic Brands in promoting a face mask and a hot water bottle.

On 18 August 2021, amid ongoing public concern about COVID-19, Mosaic Brands advertised a KN95 mask for sale on its Autograph Fashion website. The mask was prominently described as “FDA AND CE APPROVED” in the product title. By placing the CE marking on a product, which stands for Conformité Européenne (European Conformity), a manufacturer declares that the product meets all the European legal requirements for CE marking and indicates that the product has been assessed to meet high safety, health, and environmental protection requirements. Mosaic Brands falsely represented that the KN95 Mask product was FDA and CE approved when it was not.

On 26 August 2021, Mosaic Brands also promoted a hot water bottle for sale on its Katies brand website, making alleged false and misleading statements that the water bottles had been “ACCC Approved” when this was not true and the ACCC does not endorse or approve any products.

[10] https://www.tga.gov.au/import-advertising-and-supply-compliance-priorities-2022-23

Australian Product Liability + Recall contacts

Belinda Henningham
Partner (Sydney)
T: +61 2 8273 9913
belinda.henningham
@wottonkearney.com.au

Robin Shute
Partner (Melbourne)
T: +61 3 9604 7905
robin.shute@wottonkearney.com.au

Jonathan Maher
Partner (Melbourne)
T: +61 3 9604 7919
jonathan.maher@wottonkearney.com.au

Scott Macoun
Partner (Brisbane)
T: +61 7 3236 8713
scott.macoun@wottonkearney.com.au

Trent O'Neill
Special Counsel (Perth)
T: +61 8 9222 6901
trent.oneill@wottonkearney.com.au

Laura O'Toole
Associate (Sydney)
T: +61 2 9064 1818
laura.otoole@wottonkearney.com.au

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A core area of expertise for the alliance is Product Safety, Liability and Recall. Find out more here.

New Zealand Product Liability + Recall contacts

Misha Henaghan
Partner (Auckland)
T: +64 9 280 1497
misha.henaghan@wottonkearney.com

Mathew Francis
Partner (Auckland)
T: +64 9 280 0528
mathew.francis@wottonkearney.com

Natasha Cannon
Special Counsel (Wellington)
T: +64 4 974 5759
natasha.cannon@wottonkearney.com

Anna McElhinney
Special Counsel (Auckland)
T: +64 9 940 3886
anna.mcelhinney@wottonkearney.com

Jeremy Thomson
Senior Associate (Wellington)
T: +64 4 909 9718
jeremy.thomson@wottonkearney.com

Caitlin Barclay
Associate (Wellington)
T: +64 4 260 3990
caitlin.barclay@wottonkearney.com

Isabelle Kwek
Solicitor (Auckland)
T: +64 9 974 4393
isabelle.kwek@wottonkearney.com

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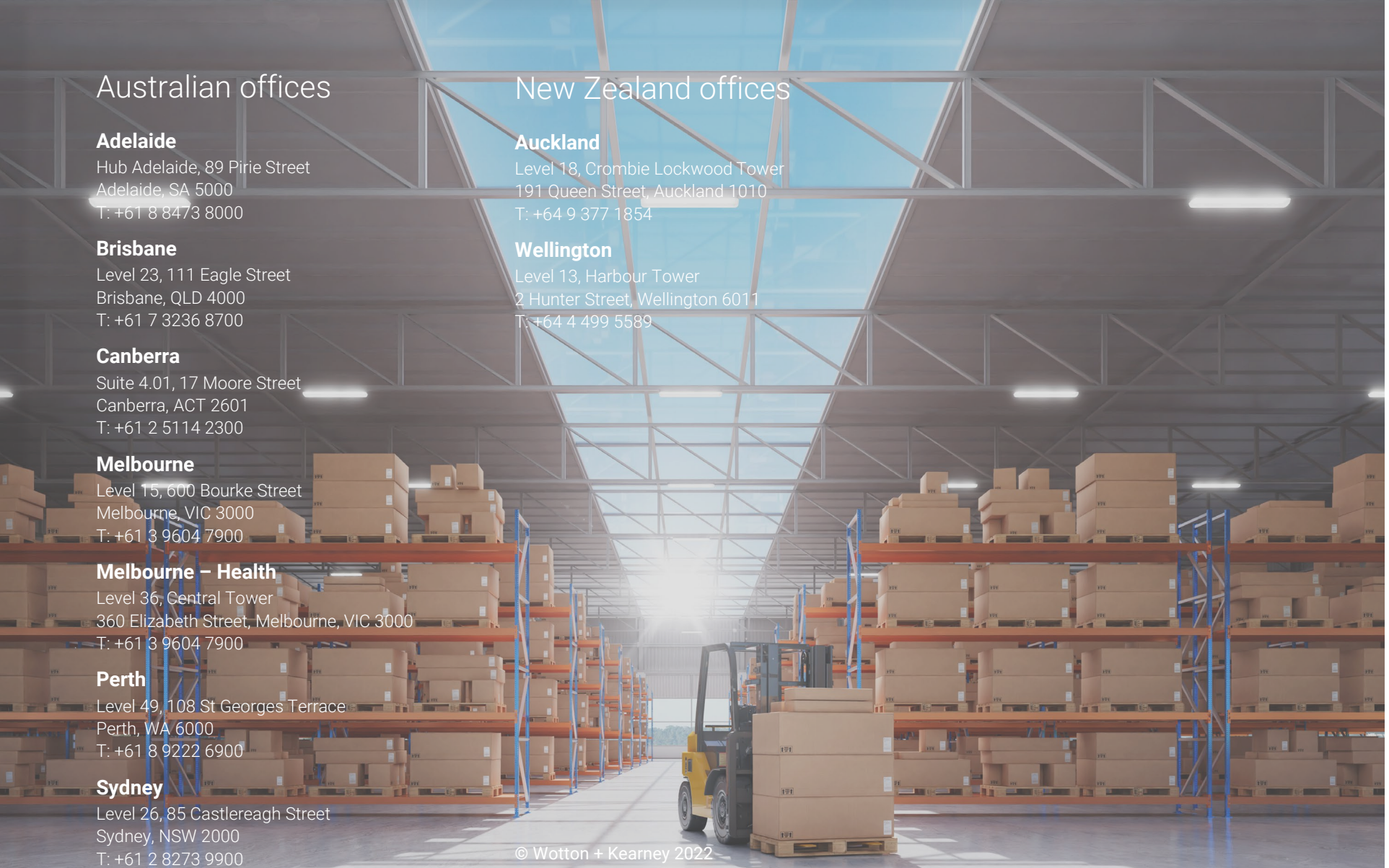

Australian offices

Adelaide
Hub Adelaide, 89 Pirie Street
Adelaide, SA 5000
T: +61 8 8473 8000

Brisbane
Level 23, 111 Eagle Street
Brisbane, QLD 4000
T: +61 7 3236 8700

Canberra
Suite 4.01, 17 Moore Street
Canberra, ACT 2601
T: +61 2 5114 2300

Melbourne
Level 15, 600 Bourke Street
Melbourne, VIC 3000
T: +61 3 9604 7900

Melbourne – Health
Level 36, Central Tower
360 Elizabeth Street, Melbourne, VIC 3000
T: +61 3 9604 7900

Perth
Level 49, 108 St Georges Terrace
Perth, WA 6000
T: +61 8 9222 6900

Sydney
Level 26, 85 Castlereagh Street
Sydney, NSW 2000
T: +61 2 8273 9900

www.wottonkearney.com.au

New Zealand offices

Auckland
Level 18, Crombie Lockwood Tower
191 Queen Street, Auckland 1010
T: +64 9 377 1854

Wellington
Level 13, Harbour Tower
2 Hunter Street, Wellington 6011
T: +64 4 499 5589

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