

Therapeutic Goods Checklist



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Contents from this checklist are taken from the Therapeutic Goods compliance register.

The LexisNexis Regulatory Compliance Therapeutic Goods Compliance Register

The Therapeutic Goods Compliance Register provides a comprehensive overview of the regulation of therapeutic goods in Australia, covering key topics such as the classification of therapeutic goods, licensing and sampling requirements, advertising of therapeutic goods, and the responsibilities of sponsors in the import, export and manufacturing of therapeutic goods. The register also delves into risk management plans, pharmacovigilance and biovigilance systems, and reporting adverse events, offering a holistic understanding of therapeutic goods in the healthcare industry. It provides guidance on the necessary policies and procedures to ensure compliance with the organisation's legal responsibilities.

About the Expert

Kelly Griffiths

Partner at Gadens



Kelly specialises in commercial disputes and investigations, with particular expertise in regulatory and law enforcement investigations. Prior to joining Gadens, Kelly worked at two top-tier Australian law firms, in the enforcement team at the Australian Securities and Investments Commission (ASIC), and as Chief Legal Counsel and Head of Government Affairs and Policy for one of the world's largest biopharmaceutical companies.

She advises clients operating in highly regulated industries, including financial services, healthcare, biotechnology, pharmaceuticals, energy and resources, FMCG, manufacturing, telecommunications, transport (aviation, heavy vehicles, rail) and technology. Kelly represents her clients in proceedings and investigations undertaken by Australia's peak regulators including ASIC, AFCA, ACCC, AFP, AUSTRAC, Border Force, TGA, OAIC, the Ombudsman, transport safety regulators and the Professional Services Review Agency. Kelly also has experience advising on multijurisdictional investigations, including by the US Department of Justice, the UK Serious Fraud Office and the US FDA.

In addition, Kelly has deep expertise in government inquiries, including advising clients appearing before Royal Commissions and other Parliamentary inquiries. This includes advising clients on public policy strategies and preparing submissions in connection with proposed legislative reform and related advocacy. Kelly was a member of the Medicines Australia task force responsible for negotiating and implementing the 2018 Strategic Agreement, and associated legislative amendments, between the innovative medicines industry and the Federal Government.

Kelly also acts in a range of general commercial disputes including contractual disputes, advertising disputes, consumer law, intellectual property, product liability, tort and administrative law actions.

She provides strategic advice in relation to financial services regulation, public sector accountability, anti-bribery and corruption, therapeutic goods regulation, and government procurement. This has included strategic advice on submissions to Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC) for reimbursement of medicines, vaccines and diagnostics, government and hospital supply tenders.

Kelly is an experienced company director in the healthcare and creative arts industries and is a member of the Human Research Ethics Committees of the Royal Children's Hospital and Murdoch Children's Research Institute. Kelly is also a member of the Advisory Council to the Victorian Health Complaints Commissioner.

Kelly is recognised as a Best Lawyer in the area of Litigation by Best Lawyers Australia.

THERAPEUTIC GOODS CHECKLIST

This checklist has been designed to help you identify your compliance requirements related to the management and supply of therapeutic goods in Australia.

Overview

Requirement	Needs work	Don't know	Meets requirement
Does the organisation have systems, policies and procedures in place to ensure it complies with all of its obligations as a sponsor of therapeutic goods in Australia?			

Identification for Therapeutic Goods

Requirement	Needs work	Don't know	Meets requirement
Does the organisation determine whether a product that it imports, exports, manufactures or supplies falls within the definition of therapeutic goods?			

Does the organisation ensure it does not import, export, manufacture or supply therapeutic goods or therapeutic goods containing certain ingredients or components, where those therapeutic goods are prohibited or restricted due to international agreements?

Does the organisation ensure that the sponsor details of the therapeutic goods it deals with are recorded correctly in the Australian Register of Therapeutic Goods (the register), and that those therapeutic goods are entered into the correct parts of the register?

Medicines

Requirement	Needs work	Don't know	Meets requirement
Does the organisation ensure medicines comply with certain standards before they are registered in the Australian Register of Therapeutic Goods (ARTG)?			

Does the organisation make an application to register prescription medicines to the Therapeutic Goods Administration?

Does the organisation make an application to register non-prescription medicines to the Therapeutic Goods Administration?

Does the organisation make an application to the Therapeutic Goods Administration to list and include a medicine on the Australian Register of Therapeutic Goods?

Does the organisation make a request to the Therapeutic Goods Administration to vary the entry of a registered or listed medicine in the Australian Register of Therapeutic Goods?

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Medical Devices

Requirement	Needs work	Don't know	Meets requirement
Does the organisation that manufactures medical devices ensure that it correctly classifies its medical devices?			
Does the organisation ensure that it complies with the essential principles for medical devices?			
Does the organisation ensure that the medical devices it manufactures have the applicable conformity assessment procedures and certification?			
Does the organisation ensure it complies with the registration requirements when listing a medical device on the Australian Register of Therapeutic Goods (ARTG)?			
Does the organisation ensure that its medical devices comply with the conditions of registration on the Australian Register of Therapeutic Goods (ARTG)?			

Biologicals

Requirement	Needs work	Don't know	Meets requirement
Does the organisation ensure that it complies with the standards for biologicals in Australia?			
Does the organisation ensure that it complies with the requirements for registration/inclusion of a Class 1 biological in the Australian Register of Therapeutic Goods (ARTG)?			
Does the organisation ensure that it complies with the requirements for registration/inclusion of a Class 2, 3 or 4 biological in the Australian Register of Therapeutic Goods (ARTG)?			
Does the organisation ensure that it complies with the conditions imposed on biologicals included in the Australian Register of Therapeutic Goods (ARTG)?			
Does the organisation ensure that it makes a request to the Therapeutic Goods Administration (TGA) in order to vary the entry of a biological in the Australian Register of Therapeutic Goods (ARTG)?			

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Sampling of Therapeutic Goods

Requirement	Needs work	Don't know	Meets requirement
Does the organisation comply with all product sampling requirements of the Therapeutic Goods Administration (TGA)?			
Does the organisation comply with all medical device sampling requirements of the Therapeutic Goods Administration (TGA)?			

Manufacturing Medicines and Biologicals

Requirement	Needs work	Don't know	Meets requirement
Does the organisation that manufactures therapeutic goods ensure that it complies with the requirements of its manufacturing licence?			
Does the organisation comply with the Good Manufacturing Principles when manufacturing medicines and biologicals?			
Does the organisation that holds a manufacturing licence comply with the requirements for varying or transferring a manufacturing licence?			

Does the organisation understand which therapeutic goods are exempt from compliance with the manufacturing principles?

Labelling, Packaging and Patient Information

Requirement	Needs work	Don't know	Meets requirement
Does the organisation ensure that it complies with the requirements for labelling medicines?			
Does the organisation ensure that it complies with the requirements for labelling biologicals and HCT materials?			
Does the organisation ensure that medicines are supplied with a Consumer Medicines Information that meets all the required information?			
Does the organisation ensure that it complies with the child-resistant packaging requirements for medicines?			

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Licensing for Wholesale Supply

Requirement	Needs work	Don't know	Meets requirement
Does the organisation have authorisation in the Australian Capital Territory to supply regulated therapeutic goods and/or substances by wholesale?			
Does the organisation have authorisation in New South Wales to supply poisons and/or restricted substances for therapeutic use by wholesale?			
Does the organisation have authorisation in the Northern Territory to supply scheduled substances by wholesale?			
Does the organisation have authorisation in Queensland to supply regulated substances by wholesale?			
Does the organisation have authorisation in South Australia to supply scheduled poisons and medicines by wholesale?			
Does the organisation have authorisation in Tasmania to sell or supply scheduled substances by wholesale?			
Does the organisation have authorisation in Victoria to sell or supply poisons and controlled substances by wholesale?			
Does the organisation have authorisation in Western Australia to sell or supply medicines or poisons by wholesale?			

Advertising

Requirement	Needs work	Don't know	Meets requirement
Does the organisation ensure that it obtains prior approval from the Therapeutic Goods Administration (TGA) if it wishes to use restricted representations in the advertising of therapeutic goods?			
Does the organisation ensure that it does not use prohibited representations in the advertising of therapeutic goods to consumers without prior permission from the Therapeutic Goods Administration (TGA)?			
Does the organisation ensure that its advertising complies with the Therapeutic Goods Advertising Code?			
Does the organisation ensure that it complies with the specified provisions of the Therapeutic Goods Advertising Code and with any formal requests for information or documents in relation to the dissemination of generic information about therapeutic goods?			

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Pharmacovigilance Responsibilities

Requirement	Needs work	Don't know	Meets requirement
Does the organisation have a nominated person who will be responsible for ensuring that the organisation fulfils its pharmacovigilance responsibilities?			
Does the organisation have an effective pharmacovigilance system established to manage its pharmacovigilance responsibilities?			
Does the organisation appropriately report significant safety issues and other safety issues to the Therapeutic Goods Administration (TGA)?			
Does the organisation report any adverse events to the Therapeutic Goods Administration (TGA)?			

Biovigilance Responsibilities

Requirement	Needs work	Don't know	Meets requirement
Does the organisation have a biovigilance system established to manage its biovigilance responsibilities?			
Does the organisation report any adverse events associated with a biological to the Therapeutic Goods Administration (TGA)?			
Does the organisation report to the Therapeutic Goods Administration (TGA) any safety concerns associated with a biological that are a serious threat to public health?			

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Reports and Records

Requirement	Needs work	Don't know	Meets requirement
If a medicine faces a shortage, or a decision is made to discontinue its supply in Australia, does the organisation report this to the Therapeutic Goods Administration (TGA)?			
Does the organisation provide a six-monthly report to the Therapeutic Goods Administration (TGA) regarding the supply of exempt, approved or authorised therapeutic goods under the Special Access Scheme (SAS) and the Authorised Prescriber Scheme (APS)?			
Does the organisation report on any adverse events arising from medical devices to the Therapeutic Goods Administration (TGA), as a condition of the inclusion of the relevant medical devices in the Australian Register of Therapeutic Goods (ARTG)?			
Does the organisation that has a therapeutic good included in the Australian Register of Therapeutic Goods (ARTG) keep certain records relating to the therapeutic good?			

Therapeutic Goods Administration Enforcement

Requirement	Needs work	Don't know	Meets requirement
Does the organisation ensure that it complies with any search or inspection conducted by the Therapeutic Goods Administration (TGA) in relation to any premises involved in the production of therapeutic goods?			
Does the organisation ensure that it complies with the uniform recall procedure when conducting recall and non-recall actions relating to therapeutic goods?			
Does the organisation ensure that it complies with any request for information or documents from the Therapeutic Goods Administration (TGA)?			
Does the organisation that is a manufacturer of therapeutic goods ensure that it complies with any request for information or documents from the Therapeutic Goods Administration (TGA)?			
Does the client organisation engage labour-hire staff (or similar) and exercise control or direction over such staff which could be deemed a triangular employment relationship, and if so, does the client organisation treat such staff fairly and reasonably so that they cannot be said to have caused or contributed to a personal grievance?			
Does the organisation have policies and procedures in place to prevent or otherwise respond to workplace bullying?			

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Dismissal

Requirement	Needs work	Don't know	Meets requirement
Does the organisation only dismiss employees after following a fair process and providing a reasonable notice period, and does it supply, on request, statements of reasons for dismissal?			
Does the organisation only dismiss employees for justifiable reasons and after following a fair process?			
Does the organisation provide, on request, a statement of reasons for dismissal?			

Grievances and Authorities

Requirement	Needs work	Don't know	Meets requirement
Does the organisation cooperate with investigations and does it meet the conditions of notices and orders issued by labour inspectors, the Employment Relations Authority and the Employment Court?			
Does the organisation attempt to resolve personal grievances raised by employees?			
Does the organisation allow labour inspectors to access workplaces to perform investigations and does it provide them with documents on request?			
Does the organisation participate in Employment Relations Authority investigations?			
Does the organisation attend and cooperate with hearings in the Employment Court?			
Does the organisation ensure it has policies and processes in place that support employees to make protected disclosures and maintain the confidentiality of any disclosures made?			
Does the organisation meet the conditions of compliance orders issued by the Employment Relations Authority or the Employment Court?			

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Does the organisation never employ a person as an officer or allow them to be involved in the hiring of employees in defiance of a banning order?			
Does the organisation fulfil the terms of any enforceable undertakings agreed with a Labour Inspector?			
Does the organisation implement the changes required by improvement notices before the specified date?			
Does the organisation pay the amount specified in a demand notice, or lodge an objection with the Authority?			
Does the organisation apply to the Court of Appeal within 28 days if it wishes to appeal a decision made by the Employment Court?			

Business Restructures

Requirement	Needs work	Don't know	Meets requirement
Does the organisation facilitate the transfer of protected workers between employers, if the workers choose to transfer their employment during a business restructure, by providing the necessary information, making the required disclosures, and negotiating in good faith?			
Does the organisation facilitate the transfer of protected workers between employers if they choose to transfer their employment during a business restructure?			
Does the organisation negotiate redundancy payments with any protected employees who transfer their employment to the organisation during a restructuring but whose services are not required?			
Does the organisation disclose, on request, individual employee information and employee transfer cost information to the prospective new employers of transferring workers?			
Does the organisation apportion the costs of the outstanding entitlements of transferring workers between itself and the other employers who are parties to the transfer?			

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Strikes and Lockouts

Requirement	Needs work	Don't know	Meets requirement
Does the organisation only conduct lawful lockouts, only seek an injunction to break an unlawful strike, notify unions and authorities in advance of lockouts, give notice to the public of lockouts or strikes that will affect passenger road and rail transport services?			
Does the organisation notify employees, unions and authorities before commencing a lockout?			
Does the organisation provide additional notice before commencing a lockout that will affect an essential service and may impact the public interest?			
Does the organisation keep records and perform the prescribed notifications during a strike?			
Does the organisation suspend employees before ceasing to pay their wages during a strike?			
Does the organisation keep a record of strikes and lockouts?			

Record Keeping and Privacy

Requirement	Needs work	Don't know	Meets requirement
Does the organisation keep records demonstrating that employees receive their entitlements, does it allow employees to access and make corrections to their personal information, and does it ensure that employees are aware of any workplace surveillance programs?			
Does the organisation keep records demonstrating that employees receive their minimum entitlements?			
Does the organisation keep accurate wages and time records at all times?			
Does the organisation keep accurate holiday and leave records at all times?			
Does the organisation allow employees to access and correct personal information on request?			
Does the organisation inform employees of workplace surveillance measures when practicable?			

Your Free Demonstration.

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