Module	**THERAPEUTIC GOODS**
Jurisdictions	**CTH, NSW, VIC, SA, TAS, WA, NT, QLD, ACT**
Legal Expert	**KELLY GRIFFITHS** Partner at Gadens https://www.gadens.com/people/kelly-griffiths/ https://www.linkedin.com/in/kellyegriffiths/

Module Application

Does your organisation deal in goods classified as therapeutic goods in Australia?

Does your organisation understand and comply with its Biovigilance and Pharmacovigilance responsibilities?

Does your organisation comply with the State and Territory-based licensing requirements for the supply of therapeutic goods?

Module Scope

The term 'therapeutic goods' encompasses a wide range of products and substances, including medicines, vaccines, medical devices and biologicals that are represented to be, or are likely to be taken to be, for therapeutic use. 'Therapeutic use' includes use in, or in connection with:

- Preventing, diagnosing, curing, or alleviating a disease, ailment, defect or injury
- Influencing, inhibiting or modifying a physiological process
- Testing the susceptibility of persons to a disease or ailment
- Influencing, controlling or preventing conception
- Testing for pregnancy
- Replacing or modifying parts of human anatomy, or
- Administering a substance or product to achieve any of the purposes specified in the above points

Therapeutic goods are regulated primarily under the Therapeutic Goods Act 1989 (Cth) and the associated regulations and standards. The Therapeutic Goods Administration (TGA) is the regulatory authority responsible for implementing and enforcing these regulations and standards.

The regulatory framework in Australia involves a comprehensive process of assessment, registration, and post-market surveillance to ensure the safety, quality and efficacy of therapeutic goods. The TGA assesses, grants approval and lists/registers therapeutic goods on the Australian Register of Therapeutic Goods (ARTG). The ARTG acts as a comprehensive database providing information on therapeutic goods' safety, efficacy and quality to healthcare professionals, consumers, and other regulatory authorities. The TGA also conducts post-market surveillance to monitor the safety of therapeutic goods, enforces compliance with regulatory standards, and provides ongoing guidance and information to sponsors of therapeutic goods, including healthcare professionals and the public.

The THERAPEUTIC GOODS module 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 module 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.

The specific questions and answers covered by the module are:

- What goods are categorised as therapeutic goods?
- How are therapeutic goods regulated?
- What are the responsibilities and activities of sponsors of therapeutic goods?
- What policies and procedures should a sponsor have in place to ensure that it complies with all of its legal obligations associated with therapeutic goods?
- What are the consequences if these legal obligations are breached?

By providing in-depth information and guidance, the THERAPEUTIC GOODS module equips organisations with the knowledge needed to fulfill their obligations as sponsors within the Australian market.

The legislative and regulatory landscape from which the primary legal obligations are derived include:

- Therapeutic Goods Act 1989 (Cth)
- Therapeutic Goods Regulations 1990 (Cth)
- Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
- Therapeutic Goods (Conformity Assessment Standard for Quality Management Systems) Order 2019 (Cth)
- Therapeutic Goods (Manufacturing Principles) Determination 2020 (Cth)
- Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines (Cth)

- Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines (Cth)
- Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017 (TGO 95) (Cth)
- Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 (Cth)
- Therapeutic Goods (Reportable Medicines) Determination 2018 (Cth)
- Therapeutic Goods (Biologicals—Conditions of Inclusion in Register) Determination 2018 (Cth)
- Criminal Code 1995 (Cth)
- Customs Act 1901 (Cth)
- Medicines, Poisons and Therapeutic Goods Act 2008 (ACT)
- Medicines, Poisons and Therapeutic Goods Regulation 2008 (ACT)
- Poisons and Therapeutic Goods Act 1966 (NSW)
- Poisons and Therapeutic Goods Regulation 2008 (NSW)
- Medicines, Poisons and Therapeutic Goods Act 2012 (NT)
- Medicines and Poisons Act 2019 (Qld)
- Medicines and Poisons (Medicines) Regulation 2021 (Qld)
- Controlled Substances Act 1984 (SA)
- Controlled Substances (Poisons) Regulations 2011 (SA)
- Poisons Act 1971 (Tas)
- Drugs, Poisons and Controlled Substances Act 1981 (Vic)
- Medicines and Poisons Act 2014 (WA)
- Medicines and Poisons Regulations 2016 (WA)

Significant consequences can apply to Australian organisations, their employees and authorised individuals found to have breached or not complied with their legal obligations. These consequences vary considerably depending on the nature and extent of the breach or failure. The THERAPEUTIC GOODS module covers specific consequences in detail which can include significant monetary penalties, terms of imprisonment and suspension or termination of certain licences.

The THERAPEUTIC GOODS module covers the roles and responsibilities of importers, exporters, suppliers and manufacturers of therapeutic goods. The module does not cover the role or actions to be taken by consumers in the event of a breach of regulations or obligations by an organisation.

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