

# Regulatory

Our lawyers have significant experience in advising on the regulatory issues involved in the pharmaceutical, agricultural chemical, medical devices and biotechnology industries, all industries that are highly regulated in Australia

We advise our clients on various regulatory issues, including:

- the operation and effect of the *Australian Therapeutic Goods Act 1989* (Cth), associated regulations;
- the role of, operations and decisions of the Therapeutic Goods Administration (Australia's equivalent body to the **US FDA**);
- the registration and approval processes for therapeutic goods and medical devices in Australia;
- the regulatory approval process for agricultural chemicals;
- clinical trial regulation in Australia, including clinical trial agreements and GCP compliance;
- the Commonwealth pharmaceutical reimbursement program, the **PBS**;
- genetically modified organism (**GMO**) regulation;
- biodiversity legislation;
- functional foods and nutraceuticals;
- food standards and GM food labelling issues.

Many of the regulatory approval processes involved in these industries include the ability for administrative reviews of decisions made by regulatory bodies. We have advised and acted for several entities seeking to challenge decisions made by regulatory bodies, including seeking information on decisions (through FOI applications), internal administrative reviews and the institution of Federal Court proceedings under the *Commonwealth Administrative Decisions (Judicial Review) Act*.

## Recent matters representative of our experience include:

- Advising a number of pharmaceutical companies on issues relating to the giving of certificates to the Therapeutic Goods Administration under s26B of the *Therapeutic Goods Act*.
- Advising in relation to the regulatory regime in Australia for the approval of Similar Biological Medicinal Products (bio-similars).
- Advising a supplier of medical device products in relation to the obligations to report adverse events.

## Key contacts

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