Life Sciences and Health Care

大成 DENTONS KENSINGTON SWAN

Overview

In the highly regulated medical and pharmaceutical sectors, failure to comply with the law can result in criminal convictions, large fines, reputational damage, and the loss or suspension of licences or product consents.

Dentons Kensington Swan provides expert advice to guide and protect clients providing products and services in this environment including:

- overseas companies without a New Zealand presence on a range of matters, including regulatory advice, agency and sponsorship arrangements
- pharmaceutical and medical device providers dealing with Pharmac and District Health Boards in contract negotiations for the supply of medicines and medical devices and the negotiation of clinical study agreements and indemnities
- providers of health care and aged care services
- on medical practice acquisitions
- health industry training organisations
- regulatory bodies such as the Medical Council.

Medicines Act Compliance

Up-to-date and accurate advice is critical for companies undertaking clinical trials or supplying therapeutic products, including medicines, medical devices, cosmetics, and related products.

We can advise clients on compliance with the Medicines Act on issues such as:

- sponsorship
- importation
- distribution
- product labelling
- licensing
- conducting clinical trials
- advertising therapeutic products.

Clinical trials

We can assist with drafting and negotiating contracts, agreements and corresponding indemnities with research organisations to comply with specific guidelines published by Medsafe and the Researched Medicines Industry Guidelines on compensation.

Contract Negotiation and Funding Agreements

We regularly assist a number of multinational clients in contract negotiations with Pharmac, District Health Boards, and other purchasers of medicines, medical devices, and related products. We are familiar with the complexities that arise when central buying agencies are contracting parties, and the care that needs to be taken to ensure the effects of such arrangements are fully understood. We have recently advised one such client on Pharmac's ability to de-list a product, and assisted the client in dealing with a dispute with Pharmac relating to that client's ability to terminate supply under a listing agreement that had no express duration.

Assisted Reproductive Technology

We advise clients on the legislation and regulations around assisted reproductive technology, including the Human Assisted Reproductive Technology Act 2004 and associated regulations, the Code of Health and Disability Services Consumers' Rights, the Human Tissue Act 2008, and Fertility Services Standard.

Overseas Companies

We assist overseas companies without a New Zealand presence to deal with regulatory matters, including agency and sponsorship arrangements. Regulation in this area is not confined to easy-to-use legislation, and familiarity with a range of guidelines is required, as is a good knowledge of industry practice.

Professional Regulation and Discipline

Dentons Kensington Swan is one of New Zealand's leading advisers on professional regulation and professional discipline within the health sector. We advise Responsible Authorities, Professional Conduct Committees, employers and individual practitioners on their professional and ethical obligations under the Health Practitioners Competence Assurance Act and the relevant ethical standards and codes in the health profession.

Your Key Contacts

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