



Life Sciences

in 24 jurisdictions worldwide

Contributing editors: Alexander Ehlers and Cord Willhöft

2010



Published by
GETTING THE DEAL THROUGH
in association with:

Advokaadibüroo bnt Attorneys-at-law
Anderson Mōri & Tomotsune
Arnold & Porter (UK) LLP
Beslay + Le Calvé
Biolato Longo Ridola & Mori
bnt Attorneys APB
bnt Klauberg Krauklis, Attorneys at Law
bnt legal & tax Minsk
Bowman Gilfillan
Brudkowski and Partners
Bruun & Hjejle
Dewallens & partners
DLA Piper LLP
Ehlers, Ehlers & Partner
Griffith Hack Lawyers
Lopes Dias & Associados
Matheson Ormsby Prentice
Mattos Muriel Kestener Advogados
Preslmayr Rechtsanwälte OG
Rajinder Narain & Co
Schönherr
Setterwalls Advokatbyrå AB
Szecskay Attorneys at Law
Wenger & Vieli AG



Life Sciences 2010

Contributing editors

Alexander Ehlers and Cord Willhöft
Ehlers, Ehlers & Partner

Business development manager
Joseph Samuel

Marketing managers

Alan Lee
Dan Brennan
George Ingledew
Edward Perugia
Robyn Hetherington
Dan White
Tamzin Mahmoud
Ellie Notley

Subscriptions manager

Nadine Radcliffe
Subscriptions@
GettingTheDealThrough.com

Assistant editor

Adam Myers

Editorial assistant

Nick Drummond-Roe

Senior production editor

Jonathan Cowie

Chief subeditor

Jonathan Allen

Production editor

Joanne Morley

Senior subeditor

Kathryn Smuland

Subeditors

Laura Zühiga
Ariana Frampton
Charlotte Stretch

Editor-in-chief

Callum Campbell

Publisher

Richard Davey

Life Sciences 2010

Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910
© Law Business Research Ltd
2009

No photocopying: copyright
licences do not apply.

ISSN 2042-4329

The information provided in this publication is general and may not apply in a specific situation. Legal advice should always be sought before taking any legal action based on the information provided. This information is not intended to create, nor does receipt of it constitute, a lawyer-client relationship. The publishers and authors accept no responsibility for any acts or omissions contained herein. Although the information provided is accurate as of November 2009, be advised that this is a developing area.

Printed and distributed by
Encompass Print Solutions.
Tel: 0870 897 3239

Law

Business

Research

Introduction Cord Willhöft <i>Ehlers, Ehlers & Partner</i>	3
Australia Wayne Condon <i>Griffith Hack Lawyers</i>	4
Austria Rainer Herzig and Bernhard Wieczorek <i>Preslmayr Rechtsanwälte OG</i>	8
Belarus Alexander Liessem and Anna Kozlova <i>bnt legal & tax Minsk</i>	13
Belgium An Vijverman <i>Dewallens & partners</i>	17
Brazil Beatriz MA Camargo Kestener, Beatriz Veiga Carvalho and Rubens Granja <i>Mattos Muriel Kestener Advogados</i>	23
Czech Republic Jiří Hrádek and Michaela Zemanová <i>Schönherr</i>	29
Denmark Poul Heidmann and Nicolaj Kleist <i>Bruun & Hjejle</i>	34
Estonia Mirjam Vili and Mark Butzmann <i>Advokaadibüroo bnt Attorneys-at-law</i>	38
France Laure Le Calvé <i>Beslay + Le Calvé</i>	43
Germany Cord Willhöft and Alexander Ehlers <i>Ehlers, Ehlers & Partner</i>	49
Hungary Sándor Németh and Stefan Moldovan <i>Szecskey Attorneys at Law</i>	55
India Ravi Nath <i>Rajinder Narain & Co</i>	60
Ireland John O'Connor, Tom Hayes, Alistair Payne and Valerie Shaw <i>Matheson Ormsby Prentice</i>	66
Italy Linda Longo and Andrea Moretti <i>Biolato Longo Ridola & Mori</i>	70
Japan Junichi Kondo, Yoshikazu Iwase, Shiho Koizumi, Wakako Sekiyama, Kensaku Yamamoto and Yumiko Yoneda <i>Anderson Mōri & Tomotsune</i>	76
Latvia Theis Klauberg and Renars Gasuns <i>bnt Klauberg Krauklis, Attorneys at Law</i>	81
Lithuania Giedre Dailidenaite and Theis Klauberg <i>bnt Attorneys APB</i>	86
Poland Bartosz Kaczmarek <i>Brudkowski and Partners</i>	91
Portugal Maria de Lourdes Lopes Dias and Paula Neves Ramalho <i>Lopes Dias & Associados</i>	96
South Africa Llewellyn Parker <i>Bowman Gilfillan</i>	101
Sweden Odd Swarting and Camilla Appelgren <i>Setterwalls Advokatbyrå AB</i>	106
Switzerland Frank Scherrer <i>Wenger & Vieli AG</i>	111
United Kingdom Lincoln Tsang and Jeremy Willcocks <i>Arnold & Porter (UK) LLP</i>	116
United States Kimberly K Egan and Rebecca Jones McKnight <i>DLA Piper LLP</i>	122

Australia

Wayne Condon

Griffith Hack Lawyers

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

Health care in Australia is composed of a combination of public and private-sector service providers.

The health-care system is supported by various overarching government bodies and schemes that serve to regulate and fund both health care and medical services and access to pharmaceuticals and other such medical or therapeutic goods.

Broadly, the Australian government (at the federal level) conceives health-care policy with respect to funding and regulation, whereas state and municipal governments are responsible for the regulation of health-care professionals (including those operating in both the private and public sectors), the provision of public hospitals and health-care services and regulating private health-care services and hospital.

2 How is the health-care system financed in the outpatient and inpatient sectors?

The structure of the Australian health-care system, across both the outpatient and inpatient sectors, is designed to ensure all Australian citizens have access to medical care.

Taxes and levies paid by Australians finance the health-care system. The amount of tax paid by each Australian is dependent upon the individual's income. Additionally, a large number of health-care services are financed privately via private health insurance.

Australians who elect to take up private health insurance are entitled to more choice with respect to particular private-sector health and medical services and providers. As an incentive to promote private health insurance, the Australian federal government offers a 30 per cent rebate on fees to all Australians taking out private health insurance policies.

Australians electing to be treated as public patients may still receive health and medical care for free or at a reduced cost from public-sector hospitals. These public-sector hospitals are funded jointly by the Australian federal government and the various state governments.

Subsidised medical care, for both inpatients and outpatients and within both the private and public sectors, is coordinated by a federal government agency called Medicare Australia (Medicare). The subsidies offered by Medicare can be accessed by all Australians.

Pursuant to the subsidies offered by Medicare, public patients can obtain free medical treatment or health-care services from a public-sector hospital, or subsidised treatment for certain treatments or services received from private medical or health-care providers (including optometrists and dentists).

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

There are a number of pieces of legislation that govern the advertisement of medicinal products to the general public and health-care professionals in Australia.

Consumer law protection in Australia is provided primarily by means of the Trade Practices Act 1976 (the TP Act). This Act broadly governs the conduct of corporations in their dealings with consumers, including advertising.

More specifically, advertisements for medicinal goods (and other therapeutic products) are governed by the Therapeutic Goods Act 1989 (the TG Act). The TG Act is administered by a federal government body called the Therapeutic Goods Administration (the TGA). Among a number of other functions, the TGA is primarily responsible for ensuring therapeutic goods available in Australia are of an acceptable standard.

In addition, there are a number of codes of conduct that must (according to the Therapeutic Goods Act) be complied with by companies when advertising medicinal products.

In particular, any advertisements that are aimed directly at consumers must comply with the Therapeutic Goods Advertising Code developed by the TGA and the Medicines Australia Code of Conduct. Direct advertising of prescription products to consumer is not, however, permitted in Australia.

Medicines Australia, an association of companies involved in the Australian pharmaceuticals industry, has developed a code of conduct (binding only to its members) that sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia. This code is self-regulating and complements the legislative requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Act.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

Advertising of medicinal products, including prescription medications, to health-care professionals is permitted in Australia.

It is a requirement under the TG Act that therapeutic goods be included on a register maintained by the TGA – the Australian Register of Therapeutic Goods (ARTG) – before they can be advertised (or in fact, supplied) in Australia.

It is not necessary to receive approval regarding the content or form of an advertisement from any organisation prior to advertising pharmaceutical products to health-care professionals.

It is important that all advertisements in Australia, regardless of the audience to whom the advertisement is directed, be true and accurate, and not misleading or deceptive in any way.

The Medicines Australia Code of Conduct specifically requires that all advertisements to health-care professionals include:

- accurate information regarding the particular pharmaceutical product's status with respect to the Pharmaceutical Benefits Scheme (PBS) and the price of the product under the PBS (if listed);
- the brand name of the product;
- the name of the active ingredient of the product as listed with the Australian Register of Therapeutic Goods (ARTG);
- the name and address of the supplier of the product;
- information about the product (specifically regarding the uses and limitations of the product, the required dosage, precautions and contraindications – the product information); and
- a statement that the health-care professional refer the user to the product information.

5 What are the main rules and principles applying to advertising aimed at the general public?

Advertisements for medicinal products aimed at the general public are permitted in Australia, except in relation to prescription medications.

Generally, an advertisement to the general public must not:

- be directed to children under 18 years of age;
- be misleading or deceptive in any way, especially in relation to the promotion of unrealistic expectations of product performance, or that there are no side effects associated with the use of the product;
- exploit the lack of knowledge of the general public; or
- provide any incentives to non-health-care professionals involved in the retail sale of the product.

6 What are the most common infringements committed by manufacturers with regard to the advertisement rules?

The Medicines Australia Code of Conduct Committee determinations are published on the Medicines Australia website on a quarterly and annual basis at www.medicinesaustralia.com.au. By far the majority of complaints relate to false and misleading advertising.

7 Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

The Medicines Australia Code of Conduct prevents the promotion of unapproved indications for pharmaceutical products that have otherwise been approved and registered by the TGA (ie, off-label use).

It is, however, permissible to provide educational material to health-care professionals regarding unapproved indications at international and Australasian congresses, provided that such material clearly states that the particular indication is not approved for use in Australia. 'Congresses' are defined within the Medicines Australia Code of Conduct as being events that are sponsored by a society, college, university or other non-company entity.

8 Which legislation governs the collaboration of the pharmaceuticals industry with health-care professionals?

The TG Act, the TP Act and the relevant Codes of Conduct referred to above are the principal means by which the collaboration of the pharmaceuticals industry with health-care professionals, including medical practitioners, is governed.

9 What are the main rules and principles applying to the collaboration of the pharmaceuticals industry with health-care professionals?

The main rules and principles applying to the collaboration of the pharmaceuticals industry with health-care professionals are set out in the Medicines Australia Code of Conduct.

Generally, the Code of Conduct permits pharmaceutical companies to collaborate with health-care professionals, but requires that all such collaborations be considered ethical, in 'good taste' and able to withstand public and professional scrutiny.

In particular, the Code of Conduct requires any interaction between pharmaceutical companies and health-care professionals to be for the express purpose of enhancing the medical knowledge of the professional in respect of particular pharmaceutical products. The Code of Conduct prohibits pharmaceutical companies from offering any financial or material incentives to health-care professionals.

In circumstances where it is necessary for a pharmaceutical company to engage a consultant advisory board, the Code of Conduct emphasises the need for the pharmaceutical company to refrain from behaviour that would bring the industry into disrepute. To this end, the Code of Conduct requires there be a legitimate need for the engaging such consultant or advisory board, there be a written contractual agreement clearly setting out the relationship, records of the meetings be kept and remuneration for services rendered by the health-care professionals should be commensurate with the services.

10 What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

The provisions of Medicines Australia Code of Conduct and the Therapeutic Goods Advertising Code prescribe the type of promotion that manufacturers may undertake to health-care professionals of drugs. These provisions are commonly the subject of complaint.

11 What are the main rules and principles applying to the collaboration of the pharmaceuticals industry with patient organisations?

The Medicines Australia Code of Conduct sets out rules and principles applying to the collaboration of the pharmaceuticals industry with patient organisations.

The Code of Conduct enables pharmaceutical companies to become involved with patient groups and programmes that support patients already prescribed to take certain pharmaceutical products. Medicines Australia is chiefly concerned to ensure that companies are not viewed by the public or within the industry as engaging in unethical conduct by making any statements to the general public regarding the programme that could be considered promotional.

Any breaches of the Code of Conduct are sanctioned by Medicines Australia. Such sanctions include corrective advertising, retraction statements and, in some cases, fines paid to Medicines Australia.

12 Are manufacturers' infringements of competition law pursued by national authorities?

The Australian government is able to pursue infringements of competition law perpetrated by manufacturers in the pharmaceuticals industry.

Australian competition law is governed by the TP Act and administered by the independent government body, the Australian Competition and Consumer Commission (the ACCC).

The ACCC can pursue infringements of competition law, including the misuse of market power, anti-competitive arrangements, price fixing and boycotts (whether or not in the context of the pharmaceutical manufacturing industry), by enforcing a range of remedies such as enforceable undertakings and legal action or, alternatively, seeking to resolve the matter administratively.

The ACCC can demand sanctions including heavy fines, injunctions and other remedies including specific performance of contracts.

13 Is follow-on private antitrust litigation against manufacturers possible?

Individuals and corporations may also instigate private litigation against a manufacturer that has engaged in anti-competitive conduct

in circumstances where the aggrieved corporation or individual has a cause of action under the TPA.

Corporations and individuals engaging in private litigation are restricted to remedies of damages and injunctions.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

The regulation of the advertisement of medical devices was established in Australia in 2002 pursuant to amendments by the Therapeutic Goods Amendment (Medical Devices) Bill 2002 and the Therapeutic Goods (Medical Devices) Regulations 2002.

Similarly to the regulation of the advertisement of medicines and pharmaceutical products, when advertising medical devices, manufacturers are required to comply with the TP Act, the TG Act (and associated regulations) and the Therapeutic Goods Advertising Code.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The TG Act sets out the regulatory framework for granting marketing authorisations and placing medicines on the market.

16 Which authorities may grant marketing authorisation in your jurisdiction?

The TGA is the only authority that can grant marketing authorisations in Australia.

17 What are the relevant procedures?

Before a pharmaceutical product can be released in the Australian market, the product must be listed or registered on the ARTG.

The ARTG, established under the TG Act, is essentially a database of therapeutic goods (including both pharmaceutical and medicinal devices). In order for a pharmaceutical product to be listed on the ARTG, the TGA must grant approval for the product to be registered.

The procedures involved with obtaining marketing approval from the TGA (and registration on the ARTG) vary depending on the type of medicine proposed for registration. The ARTG includes not only prescription and pharmaceutical medicines but also complementary medicines or other such products that have some therapeutic action.

Different branches of the TGA will evaluate whether a particular medicine is approved for marketing in Australia. For instance, medicines that are deemed ‘high-risk’ medicines (such as vaccines and injectable drugs), non-prescription medicines and complementary medicines are each evaluated by a separate evaluation committee of the TGA.

However, if a medicine (or the active ingredient of a medicine) is already listed on the ARTG, the TGA will take that listing into consideration when determining whether it is necessary to evaluate the new medicine.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

The listing of a medicinal product on the ARTG does not become invalid after a certain time if the particular products have not been marketed.

19 Which medicines may be marketed without authorisation?

In Australia, no medicine or therapeutic product may be marketed without first receiving authorisation from the TGA.

20 What, according to the legislation and case law, constitute medicinal products?

In Australia, medicinal products are classified according to their function. That is, the TG Act defines a ‘medicine’ as being any therapeutic good that is represented to achieve (or is likely to achieve), its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.

A therapeutic good that is a device is not considered a ‘medicine’.

Australian legislation and case law is predominantly concerned with ‘therapeutic goods’. Therapeutic goods are defined, in the TG Act, as goods for therapeutic use (or an ingredient, component or container of therapeutic goods) where ‘therapeutic use’ means preventing, diagnosing, curing, alleviating or testing the susceptibility of a person to a disease, ailment, defect or injury; influencing, inhibiting or modifying a physiological process; influencing, controlling or preventing conception; testing for pregnancy; or the replacement or modification of parts of the anatomy in persons.

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

The regulation of the market price of medicinal products is, in practical terms, regulated by the Australian government, which administers the PBS, which operates to lower the price of pharmaceutical products to Australian consumers. The PBS is discussed in more detail below.

22 In which circumstances will the national health insurance system reimburse the cost of medicines?

The Australian federal government, through Medicare and other government authorities, will reimburse the cost of medicines in a number of circumstances.

The primary scheme aimed at reimbursing the cost of prescription medicines to Australians is the PBS, which is managed by the Department of Health and Ageing and administered by Medicare.

The register maintained by the Department of Health and Ageing, the PBS Schedule (the Schedule), lists a number of medicines that the government has decided are a necessary and cost-effective manner of maintaining the health of the Australian public.

If a particular prescription medicine is listed on the Schedule, the government will negotiate a price with the supplier of the medicine and the consumer purchase price of the medicine will then be subsidised by the federal government. All Australians, regardless of whether they have health insurance policies, are able to obtain PBS-listed medicines at the reduced price.

The subsidy is effected by payments made by Medicare to pharmacists (or directly to health-care providers in rural or remote areas). The consumer will still be required to pay a copayment toward the medicine, however, this amount is capped. In circumstances where there are multiple brands of the same medicine available, each brand of the medicine will be subsidised to the same extent but the consumer may be required to pay a premium for the preferred brand in addition to the copayment.

The Australian government also provides further subsidies for medicines required by certain veterans, financially disadvantaged Australians, indigenous Australians and individuals whose circumstances require a large number of medicines.

Medicines on the Schedule will only attract the subsidy where the medicine is prescribed for a specific therapeutic use or particular type

 Update and trends

Currently, the Therapeutic Goods Amendment (2009 Measures No. 2) Bill is being considered by the Australian parliament; this Bill will amend the TG Act. The amendments include ensuring that the classification of therapeutic goods will be handled by separate expert committees within the TGA. Costs associated with this process are to be recovered from manufacturers and importers of the therapeutic good being evaluated.

The Australian government, considering the Bill, commented that any amendments made to the TG Act should promote transparency and efforts

should be made by the Australian government to consult with industry and relevant interest groups in relation to the preparation of the legislation concerning the regulation and classification of pharmaceutical products and other therapeutic goods.

Additionally, it is expected that a new edition of the Medicines Australia Code of Conduct will be released shortly. The ACCC has approved the new Code of Conduct, expressly commending the manner in which it promotes public interest in the pharmaceuticals industry.

of patient. In such cases, the medical practitioner must declare the circumstances that require the prescription and use of such medicine.

 Medicine quality and access to information

- 23** What rules are in place to counter the counterfeiting and illegal distribution of medicines?

The prevalence of counterfeit or illegal medicines in Australia is quite low compared with the rest of the developed world. In Australia, illegal or counterfeit medicines are more likely to be imported by individuals for personal use via the internet or after international travel; commercial quantities of counterfeit or illegal medicines are rarely imported. Industry commentators have noted that Australia's small population and location is likely to be a significant deterrent to importers of commercial quantities of counterfeit medicines.

Given that the TGA closely administers and monitors all of the aspects of the pharmaceutical industry, from the development and manufacture or importation of medicines, to the supply of medicines to consumers or exportation of such medicines, there is little opportunity to make alternative modes of supply (essential 'black market' supply) workable.

The TG Act specifically states that the manufacture, importation, exportation or supply of counterfeit products is illegal. Breach of these provisions of the TG Act is a criminal offence and sanctions include fines or imprisonment (in the event that such charges are proven before the Australian courts).

- 24** What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

Information about prescription medicines is available from the Australian Government Department of Health and Ageing website at www.health.gov.au, the TGA's website at www.tga.gov.au and that of Medicines Australia (see question 6).

- 25** Outline major developments to the regime relating to safety monitoring of medicines.

The safety monitoring of medicines in Australia is undertaken by a specific office within the TGA called the Office of Medicines Safety Monitoring (the Office).

The Office is responsible for receiving and reviewing reports of adverse (including suspected adverse) reactions to prescription medicines, vaccines, pharmacy medicines and complementary medicines. In circumstances involving new medicines or where a serious adverse reaction has occurred, reviews will be conducted by the specialist Adverse Drug Reactions Advisory Committee. Once the review has been completed, details of the adverse reaction will be recorded on a database maintained by the Office.

Although there have been few changes to the pharmacovigilance reporting process in recent years, in 2003 the Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by Drug Safety and Evaluation Branch was amended to reflect changes made in the European Union concerning reporting requirements concerning the monitoring of the safety of medicines.

Griffith Hack Lawyers

 Wayne Condon

 wayne.condon@griffithhack.com.au

Level 3, 509 St Kilda Road
Melbourne 3004
Australia

Tel: +61 3 9243 8300
Fax: +61 3 9243 8333
www.griffithhack.com.au

