



**Australian
Competition &
Consumer
Commission**

GPO Box 3131
Canberra ACT 2601

23 Marcus Clarke Street
Canberra ACT 2601

tel: (02) 6243 1111
fax: (02) 6243 1199

www.accc.gov.au

Our Ref: C2009/1274
Contact Officer: Monica Bourke
Contact Phone: 02 6243 1351

16 October 2009

[Address]

Dear [Salutation]

Medicines Australia Limited - Applications for revocation and substitution [A91150, A91155-56] and applications for authorisation [A91183-84] - draft determination

The Australian Competition and Consumer Commission (the ACCC) has issued a draft determination in respect of the applications for revocation and substitution, and the applications for authorisation, lodged by Medicines Australia Limited (Medicines Australia) on 30 June 2009.

Medicines Australia is seeking authorisation for its Code of Conduct edition 16.

Draft determination

A copy of the ACCC's draft determination is available from the ACCC's website (www.accc.gov.au/AuthorisationsRegister) and by following the links to this matter. Alternatively, you can contact Monica Bourke on (02) 6243 1351 to obtain a hard copy of the draft determination. For the reasons set out in its draft determination, the ACCC proposes to grant authorisation for five years.

Next steps

Once the ACCC issues a draft determination, the applicants or any interested party may request that the ACCC convene a 'pre-decision conference'. A pre-decision conference provides the opportunity for interested parties to make oral submissions in relation to the draft determination. Conferences are conducted informally and while legal or professional advisers are able to attend they are not entitled to participate in the discussion.

If you wish the ACCC to hold a pre-decision conference in relation to the draft determination, you must notify the ACCC in writing by **2 November 2009**.

Alternatively, you are invited to make a written submission in response to the ACCC's draft determination. Submissions should be lodged by **2 November 2009**.

The ACCC will consider any submissions it receives, including any oral submissions made should a pre-decision conference be called, and will then release a final determination in relation to these applications.

Submissions will be placed on the ACCC's public register subject to any request for exclusion (guidelines are attached).

Timetable

The ACCC will continue to progress its assessment of the application in a timely manner. An updated indicative timetable is set out below for your information.

30 June 2009	Lodgement of application and supporting submission.
7 July 2009	Public consultation process begins.
October 2009	Draft determination.
October 2009	Public consultation on draft determination including any conference if called.
November/December 2009	Final determination.

This letter has been placed on the ACCC's public register. If you wish to discuss any aspect of this matter please do not hesitate to contact Monica Bourke on (02) 6243 1351.

Yours sincerely



Dr Richard Chadwick
General Manager
Adjudication Branch

Medicines Australia Draft Determination
Interested parties consulted 16 October 2009

Abbott Australasia Pty Ltd
Actelion Pharmaceuticals
AFA Healthcare Communications Council
Alchemia Limited
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
AMGEN Australia Pty Ltd
Arana Therapeutics Limited
AstraZeneca Pty Ltd
AusBiotech Ltd
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Australian Advertising Federation
Australian Medical Association
Australian Nursing Federation
Baxter Healthcare Pty Ltd
Bayer Australia Ltd
Biogen Idec Australia Pty Ltd
Biological Therapies
Biomet Australia Pty Ltd
Boehringer Ingelheim Pty Ltd
Bristol-Myers Squibb Australia
Celgene Pty Limited
CHOICE
Circadian Technologies Ltd
CMPMedica Australia Pty Ltd
Collagen Biomedical Pty Ltd
Commercial Eyes Pty Ltd
Consumers' Federation of Australia
Consumers' Health Forum of Australia
COTA (ACT)
Covance Pty Ltd
CSL Ltd
Datapharm Australia
Department of Health and Ageing
Department of Health (ACT)
Department of Health (New South Wales)
Department of Health (South Australia)
Department of Health (Queensland)
Department of Health (Western Australia)
Department of Health and Community Services (Northern Territory)
Department of Health and Human Services (Tasmania)
Department of Health and Community Services
Divisions of General Practice - ACT
Doctors' Reform Society
Dr Ken Harvey, Adjunct Senior Research Fellow, School of Public Health, La Trobe University
Eli Lilly Australia Pty Ltd

Ferring Pharmaceuticals Pty Ltd
Galderma Australia Pty Ltd
Generic Medicines Industry Association
Genzyme Australia
Gilead Sciences Pty Ltd
GlaxoSmithKline Australia
GroPep Pty Ltd
Haystac Public Affairs
Health Consumers of Rural and Remote Australia Inc
Healthy Skepticism Inc
Hexal Australia Pty Ltd
IDT Australia Limited
IMS Health Australia Pty Ltd
iNova Pharmaceuticals Pty Ltd
Ipsen Pty Ltd
Janssen-Cilag Pty Ltd
Kendle Pty Ltd
Key Pharmaceuticals Pty Ltd
KPMG
Link Medical Products Pty Ltd
Linotar Pty Ltd
Lundbeck Australia Pty Ltd
Mayne Pharma Pty Ltd
Medical Developments Australia
Medical Update Pty Ltd
Mental Illness Fellowship of Australia
Merck Serono Australia Pty Ltd
Merck Sharp & Dohme (Aust) Pty Ltd
Mundipharma Pty Ltd
National Health and Medical Research Council
National Prescribing Service Ltd
Norgine Pty Ltd
Novartis Pharmaceuticals Australia Pty Ltd
Novo Nordisk Pharmaceuticals Pty Ltd
Nycomed Pty Ltd
Office of the Parliamentary Secretary for Health
Palliative Care Australia
Parexel Australia
Pharmaceutical Health and Rational Use of Medicines, Department of Health and Ageing
Pfizer Australia
Pharmacy Guild of Australia
PharmaLink Pty Ltd (Innovex)
Pretium Pty Ltd
Princeton Publishing Pty Ltd
PriceWaterhouseCoopers
Probiotec (Australia) Pty Ltd
Progen Industries Ltd
Public Interest Advocacy Centre
Quintiles Pty Ltd

Regulatory Concepts
Roche Products Pty Ltd
Royal Australasian College of Physicians
Royal Australian College of General Practitioners
sanofi-aventis Group
Sanofi Pasteur Pty Ltd
Schering-Plough Pty Ltd
Servier Laboratories (Aust) Pty Ltd
School of Pharmacy and Medical Sciences
Shire Australia Pty Limited
Sigma Pharmaceuticals Limited
Smith & Nephew Pty Ltd
Solvay Pharmaceuticals
Stiefel Laboratories Pty Ltd
The Heart Foundation
The Pharmaceutical Society of Australia
The Society of Hospital Pharmacists of Australia
Therapeutic Goods Administration, Department of Health and Ageing
Therapeutic Guidelines Limited
UCB Pharma
Virax Holdings Ltd
Wyeth Australia Pty Ltd