Australian
Competition &
Consumer
Commission

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sent to 133
interested parties

Our Ref: C2005/1916
Contact Officer: Bronwyn Davis
Contact Phone: 02 6243 1363

5 December 2005

«Title»
«company»
«Address1»
«Address2»

Dear «Address»

Application for revocation and substitution (A90994-6)
lodged by Medicines Australia Inc

On 30 November 2005, the Australian Competition and Consumer Commission (the ACCC) received an application from Medicines Australia Inc for revocation and substitution of authorisations A90779-80.

Medicines Australia is seeking revocation of the authorisation in respect of Edition 14 of its Code of Conduct (the Code) and substitution of a replacement authorisation of Edition 15 of its Code. It is also seeking interim authorisation. The Code sets out standards of conduct for marketing of prescription products to health professionals and the relationship between the industry and members of the general public.

The ACCC and the authorisation process

The ACCC is the Australian Government agency responsible for administering the *Trade Practices Act 1974* (the Act), a key objective of which is to prevent anti-competitive conduct, thereby encouraging competition and efficiency in business, resulting in a greater choice for consumers in price, quality and service.

The Act, however, recognises that the public interest may not always be met by the operation of competitive markets. The authorisation process in the Act addresses this eventuality by allowing the ACCC to grant immunity from the application of many of the restrictive trade

practices provisions of the Act in certain circumstances. In order to grant authorisation, the ACCC must generally be satisfied that the public benefit arising from the particular conduct outweighs any detriment arising from the conduct.

In assessing the public benefits and detriments of an authorisation application, the ACCC undertakes a public consultation process seeking comments on the application from interested parties such as yourself. Following an initial consultation process, the ACCC will issue a draft decision for comment. Further information regarding the authorisation process is available from the ACCC's website (www.accc.gov.au).

Revocation and substitution of an authorisation

Under section 91C of the Act, the ACCC may grant an application to revoke an existing authorisation and grant a substitute authorisation when it is satisfied that the proposed arrangements (that is, under the substitute authorisation) would, as with the original authorisation test, result in a net public benefit. The ACCC also conducts the same public consultation process prior to making its determination.

Medicines Australia's application for revocation and substitution

In its supporting submission, Medicines Australia has outlined the provisions of Edition 15 of the Code, and the public benefits and detriments it claims will result from it.

A copy of Medicines Australia's covering letter and the supporting submission are enclosed.

A full copy of the application for authorisation, including the Final Draft of Edition 15, is available on the ACCC's website: <http://www.accc.gov.au/content/index.phtml?itemId=278039>. Alternatively, you can contact Bronwyn Davis on (02) 6243 1363 to obtain a hard copy of the application and submission.

Your views are sought

As a potentially interested party you are invited to make a written submission to the ACCC regarding the likely public benefits and detriments of the arrangements for which authorisation is sought. In particular, the ACCC would be interested in your views on the following:

- Taking into account the impact of Edition 14 of the Code and the proposed amendments in Edition 15, do you consider that the Code is effective in regulating:
  - the marketing of prescription products to health professionals and
  - the relationship between the pharmaceutical industry and the general public?

- Are there parts of the Code that you consider have not been effective and/or should be amended to improve their effectiveness?

- Do you consider that public benefits will flow from continuing to grant immunity to the Code?

- Do you consider that there might be any detriment to competition and/or the public resulting from the Code?

Medicines Australia's request for interim authorisation

As mentioned above, Medicines Australia has also requested interim authorisation to enable Edition 15 of the Code to be implemented with effect from 1 January 2005.

Interim authorisation would allow this arrangement to operate as if it had full authorisation while the substantive application is being considered by the ACCC.

The ACCC endeavours to deal with requests for interim authorisation quickly. In making an assessment as to whether it is appropriate to grant interim authorisation, the ACCC is not required to undertake a full assessment of the benefit and detriment likely to arise as a result of the proposed conduct.

The ACCC decides whether to grant interim authorisation on a case by case basis. Should an applicant request interim authorisation, the ACCC will usually consider a range of factors including harm to the applicant and other parties if interim is or is not granted, possible benefit and detriment to the public, the urgency of the matter and whether the market would be able to return to substantially its pre-interim state if the ACCC should later deny authorisation.

The ACCC is interested in your views on Medicines Australia's request for interim authorisation.

How to provide a submission

The ACCC asks for submissions to be in writing so that they can be made publicly available. Submissions are placed on a public register and may also be placed on the ACCC's website. The ACCC may, where appropriate, supplement written submissions with discussions with relevant parties on a mutually convenient basis.

Should you lodge a submission with the ACCC you may request that information included in the submission be treated as confidential and not placed on the public register or the ACCC's website. In such circumstances you must justify why the ACCC should treat such information as confidential, otherwise it would be expected to be made public. The ACCC may take confidential information into account during its assessment of an application. Guidelines for seeking confidentiality are attached for your information.

If you wish to lodge a submission, please address it to:

The General Manager
Adjudication Branch
Australian Competition & Consumer Commission
PO Box 1199
DICKSON ACT 2602

Submissions can also be lodged by email to adjudication@accc.gov.au, or by facsimile to (02) 6243 1211.

If you intend to provide a submission in relation to the substantive applications, please do so by **close of business Friday 20 January 2006.** If you wish to make a submission with regards to the interim authorisation, please provide your comments by **close of business Friday 16 December 2005.**

Please inform us if you do not wish to make a submission at this time, but would like to be informed of the progress of these applications at the draft and final determination stages. You can also forward this letter to any other party who may wish to make a submission to the ACCC regarding this application.

A copy of this letter will be placed on the ACCC's Public Register.

Should you have any queries or if you wish to discuss any aspect of this matter further, please contact Bronwyn Davis on (02) 6243 1363.

Yours «end»

Isabelle Arnaud
Director
Adjudication Branch

GUIDELINES FOR CONFIDENTIALITY CLAIMS

The process whereby the Commission assesses applications for authorisation or notification is very public, transparent and consultative. The *Trade Practices Act 1974* (the Act) requires the Commission to maintain a public register in respect of authorisation and notification applications.

Applicants and interested parties can request that a submission, or part of a submission, be excluded from the public register.

The Commission is required under the Act to exclude from the public register upon request details of:

(i) secret formulae or process;

(ii) the cash consideration offered for the acquisition of shares in the capital of a body corporate or assets of a person; or

(iii) the current manufacturing, producing or marketing costs of goods or services.

However, even if a document does not meet these technical requirements, the Commission may still grant confidentiality where, in the Commission's view, it is desirable to do so.

The Commission also has the discretion, under s89 of the Act, to exclude material from the public register if it is satisfied that it is desirable to do so, either by reason of the confidential nature of the material or for any other reason. The Commission expects that a party claiming confidentiality on these grounds will present a case for its treatment in this manner.

Under Regulation 24 of the *Trade Practices Regulations*, when a request for confidentiality is made to the Commission:

(a) where the request is that a whole document be excluded, the words **"Restriction of Publication Claimed"** should appear in red writing near the top of each page; and

(b) where the request is that part of a document be excluded, the words **"Restriction of Publication of Part Claimed"** should appear in red near the top of the first page of each document, and the part for which confidentiality is claimed should also be marked in red. A submission of more than 5 pages should also include a description of the whereabouts of the parts for which confidentiality is claimed.

Applicants, as a matter of course, should remove headers claiming "confidential communication" from all Emails and otherwise, unless they have a particular piece of information that they justify to the Commission deserves exclusion from the public register. If confidentiality is not requested but a header cannot be removed, it should be clearly stated at the beginning of the communication that confidentiality is not requested.

If the Commission denies a confidentiality request, the requesting party may ask that the material be returned. As a matter of practice, the Commission will specify a period (usually 14 days) in which they can request the return of such material. Upon response, the Commission will return the original material and destroy all associated copies. The Commission will not consider this material when reaching its decision.

If the Commission does not receive a response within the specified period, the original material will be placed on the public register.

Information or documents granted confidentiality may be used by the Commission pursuant to its powers generally under the *Trade Practices Act.*

Interested parties list. Letters sent 5 December 2005.

Title	company
The Manager	3M Pharmaceuticals Pty Ltd
The Manager	Abbott Australasia Pty Ltd
The Manager	Alcon Laboratories (Australia) Pty Ltd
The Manager	Allergan Australia Pty Ltd
The Manager	AMGEN Australia Pty Ltd
The Manager	sanofi-aventis
The Manager	Bayer Australia Ltd
The Manager	Biogen Australia Pty Ltd
Dr Robert Creek	Medical Director Boehringer Ingelheim Pty Ltd
The Manager	Bristol-Myers Squibb Australia
The Manager	CSL Ltd
Mr David Grainger	Director, Corporate Affairs and Health Economics Eli Lilly Australia Pty Ltd
The Manager	GlaxoSmithKline Australia
The Manager	Ipsen Pty Ltd
The Manager	Janssen-Cilag Pty Ltd
Mr Will Delat	Merck Sharp & Dohme (Aust) Pty Ltd
The Manager	Mundipharma Pty Ltd
The Manager	Novartis Pharmaceuticals Australia Pty Ltd
Mr Alan Taylor	Chairman Pfizer Pty Ltd
The Manager	Roche Products Pty Ltd
The Manager	sanofi-aventis Group
The Manager	Schering Pty Ltd
The Manager	Schering-Plough Pty Ltd
The Manager	Serono Australia Pty Ltd
Mr Patrick Vergauwe	General Manager Solvay Pharmaceuticals
Ms Erica Mann	Managing Director Wyeth Austraila Pty Ltd
The Manager	Sanofi-Pasteur Pty Ltd
The Manager	Smith & Nephew Pty Ltd
The Manager	Actelion Pharmaceuticals
The Manager	Zenyth Therapeutics Limited
The Manager	Institute of Drug Technology Australia Ltd
The Manager	Ferring Pharmaceuticals Pty Ltd
The Manager	Laboratoires Fournier SA
The Manager	Peptech Limited
The Manager	UCB Pharma
The Manager	Covance Pty Ltd
The Manager	ICON Clinical Research Pty Ltd
The Manager	Kendle Pty Ltd
The Manager	Quintiles Australia Pty Ltd
The Manager	Biological Therapies
The Manager	Biomet Australia Pty Ltd
The Manager	Biotech Australia
The Manager	Boucher & Muir Pty Ltd
The Manager	BresaGen Ltd
The Manager	CIBA Vision Australia Pty Ltd
The Manager	Circadian Technologies Ltd
The Manager	Collagen Biomedical Pty Ltd
The Manager	Datapharm Australia

The Manager	Ego Pharmaceuticals Pty Ltd
The Manager	ExGenix Operations Pty Ltd
The Manager	Mayne Pharma Pty Ltd
The Manager	FuCell Pty Ltd, Department of Biophysics
The Manager	Galderma Australia Pty Ltd
The Manager	Genzyme Australia
The Manager	GroPep Pty Ltd
The Manager	H W Woods Pty Ltd
The Manager	Hexal Australia Pty Ltd
Mr Tom Gregory	Managing Director Key Pharmaceuticals Pty Ltd
The Manager	Link Medical Products Pty Ltd
The Manager	Linotar Pty Ltd
The Manager	Medical Developments Australia
The Manager	Medical Research Pty Ltd
The Manager	Meditech Research
The Manager	Metabolic Pharmaceuticals Ltd
Ms Jeanys Lilley	AstraZeneca Pty Ltd
The Manager	Gilead Sciences Pty Ltd
The Manager	Organon (Australia) Pty Ltd
The Manager	ALTANA Pharma Pty Ltd
The Manager	Pretium Pty Ltd
The Manager	Princeton Publishing Pty Ltd
Dr Stuart Carr	Director, Radiopharmaceuticals ANSTO radiopharmaceuticals and industrials
The Manager	CMPMedica Australia Pty Ltd
The Manager	Gilead Sciences Pty Ltd
The Manager	Norgine Pty Ltd
The Manager	Northfield Laboratories Pty Ltd
The Manager	Novo Nordisk Pharmaceuticals Pty Ltd
The Manager	Orphan Australia Pty Ltd
The Manager	Paedpharm Pty Ltd
The Manager	Parexel Australia
The Manager	Probiotec (Australia) Pty Ltd
The Manager	Progen Industries Ltd
The Manager	Proteome Systems Ltd
The Manager	Regulatory Concepts
The Manager	SciGen Pty Ltd
The Manager	Servier Laboratories (Aust) Pty Ltd
The Manager	Stiefel Laboratories Pty Ltd
The Manager	Thrombogenix Pty Ltd
The Manager	UCB Pharma
The Manager	Virax Holdings Ltd
The Manager	Wille Laboratories
The Manager	Baxter Healthcare Pty Ltd
Mr Harry Majewski	President Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Ms Jane Halton	Secretary Department of Health & Ageing
Dr David Graham	Therapeutic Goods Administration
Dr Tony Sherbon	Chief Executive ACT Health
Ms Robyn Kruk	Director-General NSW Health
Ms Patricia Faulkner	Secretary

	Department of Human Services
Mr John Ramsay	Secretary Department of Health & Human Services
Mr Jim Birch	Chief Executive Department of Human Services
Mr Mike Daube	Director General Department of Health
Ms Uschi Schreiber	Director-General Department of Health
Mr Robert Griew	CEO Department of Health and Community Services
Dr E Robyn Mason	Secretary General, Australian Medical Association
Mr Bob Blue	Executive Officer Health Information Management Association of Australia
Professor Michael Kidd	President Royal Australian College of General Practitioners
Mr Stephen Greenwood	Executive Director Pharmacy Guild of Australia
Mr Craig Patterson	Chief Executive Officer Royal Australasian College of Physicians
Ms Jill Iliffe	Federal Secretary Australian Nursing Federation
Ms Yvonne Allinson	Executive Director The Society of Hospital Pharmacists of Australia
Mr Brian Grogan	President The Pharmaceutical Society of Australia
Ms Kate Carnell	Chief Executive Officer Australian Divisions of General Practice
Professor Ric Day	Chair, Pharmaceutical Health and Rational Use of Medicines
Dr Stephen Phillips	Chairman National Prescribing Service Ltd
Mr Chris Wills	Medical Publishers Association of Australia
Mr Chris Thomas	Australian Advertising Federation
Ms Mary Hemming	Chief Executive Officer Therapeutic Guidelines Limited
Ms Di Ford	Executive Director Generic Medicines Industry Association
Mr David Deans	Chief Executive COTA National Seniors Partnership
Ms Carmel Brophy	Project Officer Health Consumers of Rural and Remote Australia Inc
The Hon Arthur Chesterfield-Evans MLC	Australian Democrats Parliament House
Dr Jon Jureidini	Chair Healthy Skepticism
Dr Peter Eng	
Mr Martin Goddard	Health Policy Officer Australian Consumers' Association
Ms Melanie Cantwell	Director, Policy and Projects Consumers' Health Forum
Ms Catherine Wolthuizen	Chair

	Consumers' Federation of Australia
The CEO	Public Interest Advocacy Centre
Ms Nicola Ballenden	Senior Health Policy Officer Australian Consumers Association
Dr Agnes Vitry	Senior Lecturer School of Pharmacy and Medical Sciences
Dr Ken Harvey	Senior Lecturer School of Public Health
Dr Tim Woodruff	President Doctors' Reform Society
Ms Melissa Raven	Lecturer, Faculty of Health Sciences School of Medicine Flinders University