



**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: A91218 & A91219
Contact Officer: Monica Bourke
Contact Phone: 02 6243 1351

June 2010

<Address>

Dear <Salutation>

Generic Medicines Industry Association Pty Ltd (GMiA) applications for authorisation [A91218 & A91219] – request for interim authorisation

As outlined in my letter dated 7 April 2010, the Australian Competition and Consumer Commission (the ACCC) received applications for authorisation A91218-A91219 from the Generic Medicines Industry Association (GMiA) for its Code of Practice 2nd edition (Code). An amended version of the Code was provided to the ACCC on 31 May 2010 and has been placed on the ACCC's website.

On 25 June 2010, the GMiA made a request for interim authorisation. The GMiA advise that it has received a complaint about the conduct of a member company under the Code. Under the Code, complaints are dealt with initially through an internal complaints handling system and then may be referred to the GMiA's Code Complaints Committee for consideration. The GMiA advise that it is reluctant to request members of the Complaints Committee to convene to review the complaint without authorisation.

A full copy of the GMiA's request for interim authorisation is available on the ACCC's website <www.accc.gov.au/AuthorisationsRegister> and by following the links to this matter.

Request for submissions

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.

Submissions received on the substantive applications for authorisation will be taken into account when considering the request for interim authorisation. However should you wish to make any additional comments with respect to the GMiA's request for interim authorisation, you may do so by **Tuesday 6 July 2010**.

If you would like to provide comments orally, please contact Monica Bourke on (02) 6243 1351 to organise a suitable time.

Submissions, including oral submissions, will be placed on the ACCC's public register subject to any request for exclusion.

Timetable

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

31 March 2010	Lodgement of applications and supporting submission.
7 April 2010	Public consultation process begins.
29 April 2010	Closing date for submissions from interested parties.
31 May 2010	Applicant responds to issues raised in the public consultation process. Applicant provides amended version the Code.
25 June 2010	Applicant requests interim authorisation.
6 July 2010	Closing date for submissions on interim authorisation.
July 2010	ACCC decision regarding interim authorisation and draft determination.
July/August 2010	Public consultation on draft determination including any conference if called.
August/September 2010	Final determination.

You can also forward this letter to any other party who may wish to make a submission to the ACCC regarding the request for interim authorisation.

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 or via email at monica.bourke@acc.gov.au.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'R Chadwick', with a long horizontal flourish extending to the right.

Dr Richard Chadwick
General Manager
Adjudication Branch

GMiA applications for authorisation A91218-A91219
List of interested parties consulted 29.06.10

Alphapharm Pty Ltd
Apotex Pty Ltd
Ascent Pharmaceuticals (Genepharm (Australia) Limited)
Hospira Pty Limited
Sigma Pharmaceuticals Limited
Pharmacy Guild of Australia
The Pharmaceutical Society of Australia
CHOICE
National Prescribing Service Ltd
Royal Australian College of General Practitioners
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Doctors' Reform Society
Australian Nursing Federation
The Society of Hospital Pharmacists of Australia
Australian Advertising Federation
Health Consumers of Rural and Remote Australia Inc
Consumers' Federation of Australia
Public Interest Advocacy Centre
Consumers' Health Forum of Australia
School of Public Health
Royal Australasian College of Physicians
Healthy Skepticism Inc
School of Pharmacy and Medical Sciences
Australian Medical Association
Australian Psychological Society
Australian Dental Association
Australian Veterinary Practice Management Association
Australian Physiotherapy Association
Dieticians Association of Australia
Australian Institute of Medical Scientists
National Herbalists Association of Australia
Medicines Australia
Medicines Australia
Actavis Australia Pty Ltd
Alchemia Limited
Arana Therapeutics Limited
Aspen Pharmacare Australia
AusBiotech Ltd
Biological Therapies
Circadian Technologies Ltd
CMPMedica Australia Pty Ltd
Collagen Biomedical Pty Ltd
Datapharm Australia
Ferring Pharmaceuticals Pty Ltd
Galderma Australia Pty Ltd
GroPep Pty Ltd
Hexal Australia Pty Ltd

Key Pharmaceuticals Pty Ltd
Link Medical Products Pty Ltd
Mayne Pharma Pty Ltd
Medical Developments Australia
Novartis Pharmaceuticals Australia Pty Ltd
Parexel Australia
Pharmacor
Probiotec (Australia) Pty Ltd
Progen Industries Ltd
Ranbaxy Australia
Spirit Pharmaceuticals
Virax Holdings Ltd
Generic Health
Australian Pharmaceutical Industries
Department of Health and Ageing, Therapeutic Goods Administration
Department of Health and Ageing, Therapeutic Goods Administration
Department of Health and Ageing, Therapeutic Goods Administration
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)
Parliamentary Secretary for Health's Office
National Health and Medical Research Council