

Our Ref: A91218-A91219  
Contact Officer: Monica Bourke  
Contact Phone: 02 6243 1351



**Australian  
Competition &  
Consumer  
Commission**

3 August 2010

<Address>

Dear <Salutation>

*This letter, with  
enclosures, was  
sent to the attached  
list of interested parties.  
MB. 3-8-10*

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### **Generic Medicines Industry Association – applications for authorisation A91218-A91219 – draft determination**

The Australian Competition and Consumer Commission (the ACCC) has issued a draft determination in respect of the applications for authorisation lodged by the Generic Medicines Industry Association (GMiA) on 31 March 2010.

The GMiA is seeking authorisation for its Code of Practice 2<sup>nd</sup> edition.

For the reasons set out in its draft determination, the ACCC proposes to grant authorisation subject to conditions for a period of three years.

A copy of the draft determination is available on the ACCC's website <[www.accc.gov.au/AuthorisationsRegister](http://www.accc.gov.au/AuthorisationsRegister)> and by following the links to this matter.

#### **Interim authorisation**

The ACCC has granted interim authorisation to the Code so that the Code Complaints Committee can convene to consider a complaint made to the GMiA while the substantive applications are being considered.

Interim authorisation will remain in place until the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation.

#### **Next steps**

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 **Tuesday 17 August 2010**.

You are invited to make a written submission in response to the ACCC's draft determination. Submissions should be lodged by **Friday 20 August 2010**.

In the draft determination the ACCC has invited further comments from the GMiA and interested parties. In particular the ACCC seeks further information on:

- Sponsorship of healthcare professionals to attend educational events and whether generic pharmaceutical companies sponsor healthcare professionals to attend event.
- The proposed conditions of authorisation, their operation and likely compliance costs associated with the conditions.

I would appreciate receiving your views on these issues by **Friday 20 August 2010**.

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.

<b>31 March 2010</b>	Lodgement of application and supporting submission.
<b>7 April 2010</b>	Public consultation process begins.
<b>3 August 2010</b>	Draft determination and decision regarding interim authorisation.
<b>17 August 2010</b>	Deadline for requesting a pre-decision conference.
<b>20 August 2010</b>	Submissions regarding the draft determination due.
<b>September 2010</b>	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

**GMiA applications for authorisation A91218-A91219**  
**List of interested parties consulted 3 August 2010 – Draft determination**

Alphapharm Pty Ltd  
Apotex Pty Ltd  
Ascent Pharmaceuticals (Geneparm (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  
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 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  
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