



**Australian
Competition &
Consumer
Commission**

Our Ref: A91218-A91219
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3 August 2010

By email: kate.lynch@gmia.com.au

Dear Ms Lynch

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.

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

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.

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