

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

7 April 2010

<Address>

This letter, with enclosures, was sent to the attached list of interested parties.

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MB. 7/4/10.

Dear <Salutation>

Generic Medicines Industry Association Pty Ltd (GMiA) applications for authorisation [A91218 & A91219] - interested party consultation

The Australian Competition and Consumer Commission (the ACCC) has received applications for authorisation from the Generic Medicines Industry Association (GMiA). The ACCC invites you to comment on the applications. <u>Attached</u> is a summary of the authorisation process including how to make a submission to the ACCC.

The GMiA is seeking authorisation for the 2nd edition of its Code of Practice (Code). GMiA members are proposing to introduce and be bound by the Code which includes provision for taking disciplinary action against GMiA members who breach the Code.

A full copy of the applications for authorisation is available on the ACCC's website < www.accc.gov.au/AuthorisationsRegister >. Alternatively, you can contact Monica Bourke on (02) 6243 1351 to obtain a hard copy of the application and submission.

Request for submissions

The ACCC invites you to make a submission on the likely public benefits and effect on competition, or any other public detriment, from the Code. For example, you may wish to provide your views on the following:

- 1. How will the Code be effective in monitoring and regulating the conduct of GMiA member companies?
- 2. What are the public benefits likely to flow from granting authorisation to the Code?
- 3. What is the detriment to competition and/or the public resulting from the Code?

If you intend to provide a submission in relation to the GMiA's applications for authorisation, please do so by Thursday 29 April 2010.

Alternatively, 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 (guidelines are <u>attached</u>).

Timetable

The ACCC will progress its assessment of the applications 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.
May 2010	Applicant responds to issues raised in the public consultation process.
June/July 2010	Draft determination.
July/August 2010	Public consultation on draft determination including any conference if called.
August/September 2010	Final determination.

Please advise if you do not wish to make a submission at this time, but would like to be informed of the progress of the applications at the draft and final determination stages. If you are able to, please provide a nominated contact email address for future correspondence.

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

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 alternatively via email at monica.bourke@accc.gov.au.

Yours sincerely

Dr Richard Chadwick General Manager Adjudication Branch

GMiA applications for authorisation A91218-A91219 List of interested parties consulted 7.4.10

Alchemia Limited

Alphapharm Pty Ltd

Apotex Pty Ltd

Arana Therapeutics Limited

Ascent Pharamceuticals (Genepharm (Australia) Limited)

Aspen Pharmacare Australia

AusBiotech Ltd

Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists

Australian Advertising Federation

Australian Dental Association

Australian Institute of Medical Scientists

Australian Medical Association

Australian Nursing Federation

Australian Physiotherapy Association

Australian Psychological Society

Australian Veterinary Practice Management Association

Biological Therapies

CHOICE

Circadian Technologies Ltd

CMPMedica Australia Pty Ltd

Collagen Biomedical Pty Ltd

Consumers' Federation of Australia

Consumers' Health Forum of Australia

Datapharm Australia

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)

Dieticians Association of Australia

Doctors' Reform Society

Ferring Pharmaceuticals Pty Ltd

Health Consumers of Rural and Remote Australia Inc

Galderma Australia Pty Ltd

Generic Health

GroPep Pty Ltd

Healthy Skepticism Inc

Hexal Australia Pty Ltd

Hospira Pty Limited

Key Pharmaceuticals Ptv Ltd

Link Medical Products Pty Ltd

Mayne Pharma Pty Ltd

Medical Developments Australia

Medicines Australia

National Health and Medical Research Council

National Herbalists Association of Australia

National Prescribing Service Ltd

Parexel Australia

Parliamentary Secretary for Health's Office

Pharmaceutical Society of Australia

Pharmacy Guild of Australia

Probiotec (Australia) Pty Ltd

Progen Industries Ltd

Public Interest Advocacy Centre

Royal Australian College of General Practitioners

Royal Australasian College of Physicians

School of Pharmacy and Medical Sciences

School of Public Health

Sigma Pharmaceuticals Limited

The Society of Hospital Pharmacists of Australia

Therapeutic Goods Administration

Virax Holdings Ltd