Regulatory Policy & Governance Division (RPGD)

Therapeutic Goods (Codes of Conduct) Implementation Advisory Group - Terms of Reference

Terms of reference for TGIAG

In this section:

Promotion of Therapeutic Goods

Regulatory Policy & Governance Division (RPGD)

Review of Health and Medical Research in Australia

Background

The Australian Government provided \$1.4 million over four years in the 2012-13 Budget to assist the therapeutic goods industry to develop strong, consistent and enforceable codes of conduct based on a common framework of high level principles, better communication mechanisms and shared systems for complaints reporting.

Implementation Advisory Group - Scope

The Australian Government is establishing an Advisory Group as part of its response to recommendations developed by the industry-led Working Group (the Working Group) on the promotion of therapeutic goods.

The purpose of the Advisory Group is to oversee and guide implementation of the Working Group's recommendations relating to self regulation including:

- Implementation of the Working Group's high-level principles and alignment of the industry's codes of conduct;
- Establishment of communication mechanisms to support better access to information for health consumers, industry and healthcare professionals;
- Improved training for healthcare professionals and industry in relation to ethical behaviour;
- Alignment of ethical standards and requirements for healthcare professionals with the standards required for industry; and
- Development of shared complaints reporting and handling processes.

Advisory Group Role

With support from the Department of Health and Ageing, the Advisory Group will oversee the following tasks:

- 1. An independent initial review of the alignment of industry codes with the Working Group's high level framework.
- The project (financial year 2013-14) will involve engagement of a consultant, collection of data, and reporting of the findings to the Advisory Group.
- 2. The design and development of processes for an IT project to deliver a shared information system and common complaints portal, which will involve:
- determining a location or arrangement for hosting the information systems and complaints portal;

- monitoring complaints received through the complaints portal and providing relevant information about these complaints including consistency of processes and outcomes in reports to the Parliamentary Secretary; and reviewing the testing and maintenance of the shared information systems and common complaints portal from start of operation to 2015-16.
- 3. Liaison and discussion with AHPRA, national boards, professional colleges and education facilities regarding implementation of the Working Group's recommendations 10-12 throughout the period of the Budget measure.
- 4. Mechanisms to improve the coverage of strong consistent and enforceable codes of conduct.
- 5. A final evaluation and report of the effectiveness of the overarching self-regulatory framework.
- This will involve the engagement of a consultant to undertake this work (August November 2015).

Members

The Advisory Group will consist of the following members:

Professor Lloyd Sansom (Chair)	Expert Chair	88
Dr Angela Pierce	Australian Dental Association (ADA)	HCP*
Mr Troy Williams	Australian Dental Industry Association (ADIA)	Industry
Dr Gino Pecoraro	Australian Medical Association (AMA)	НСР
Ms Elizabeth Foley	Australian Nursing Federation (ANF)	НСР
Mr Steven Scarff	Australian Self Medication Industry (ASMI)	Industry
Ms Alina Tooley	AusBiotech	Industry
Mr Richard Henfrey	Complementary Healthcare Council of Australia (CHC)	Industry
Ms Anne McKenzie	Consumers Health Forum of Australia (CHF)	Consumer
Ms Kate Lynch	Generic Medicines Industry Association (GMiA)	Industry
Mr Graeme Bulman	IVD Australia	Industry
Dr Brendan Shaw	Medicines Australia (MA)	Industry
Ms Anne Trimmer	Medical Technology Association of Australia (MTAA)	Industry
Mr Grant Kardachi	Pharmaceutical Society of Australia	НСР
Ms Anne Develin	The Pharmacy Guild of Australia	НСР
Or Catherine Streeton	The Royal Australian College of Physicians (RACP)	НСР

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-	Professor Alan Bensoussan	Centre for Complementary Medicine Research	HCP

^{*}Healthcare Professional

To ensure the right level and mix of knowledge, other participants/experts may be identified by the Advisory Group to attend meetings and/or provide advice on relevant areas of activity.

Period of Operation

The Advisory Group is established as a time-limited committee for a four year period commencing from December 2012 to end June 2016.

Meeting Format and Schedule

Subject to necessary adjustments in priorities that may arise, the Advisory Group is expected to hold face to face meetings every six months and ad hoc teleconferences where necessary. The meetings will be scheduled at the first meeting of the Advisory Group but can be adjusted with the agreement of members.

Secretariat

The organisation of Advisory Group meetings, including development of agendas and minutes on action items, will be undertaken by the Regulatory Policy and Governance Division of the Department of Health and Ageing as secretariat in consultation with the Chair. An Agenda and outcome of meetings will be produced by the secretariat and distributed to all Advisory Group members. Papers developed as part of the Advisory Group's work will be circulated to other members of the Group to facilitate cross communication on the issues as well as to enhance integration, consistency and coherency of ideas and approaches.

Reporting

The Advisory Group will provide a report on its activities to the Parliamentary Secretary within one month following each Advisory Group meeting or within six months following the last Advisory Group meeting, and/or on specific tasks as requested by the Parliamentary Secretary. The reports to the Parliamentary Secretary will provide updates on progress in implementation of the Working Group's recommendations (1-3, 4, and 8-17). Following the establishment of the common complaints portal, the reports will contain an analysis and information about complaints received through the portal in the reporting period, including in relation to consistency of complaints processes and outcomes, non-members and breaches of industry codes of conduct.

Communication with related committees

The therapeutic industry's initiative to strengthen self-regulation in the promotion of therapeutic goods is part of a range of reforms across the sector set out in the *TGA reforms: A blueprint for the TGA's future* (the Blueprint) released in December 2011. The Advisory Group is expected to communicate with related committees involved in reforms in the therapeutic goods sector, as identified by the Department. This will include the high-level steering committee that has been established to oversight all aspects of the implementation of reforms under the Blueprint.

Confidentiality

All papers, reports and resolutions are confidential to the Advisory Group and relevant departmental staff, unless otherwise agreed to by the Advisory Group.