

Medicines Australia Code of Conduct

Lodging a complaint – Non-industry Complainant

This advice has been provided for the benefit of healthcare professionals, members of the general public or any non-pharmaceutical industry organisation who may wish to lodge a complaint under the Medicines Australia Code of Conduct.

We have tried to make it as comprehensive, accurate and up to date as possible. If you can't find the information that you need in this document, please contact the Code of Conduct Secretariat (details on next page)

This document contains the following information:

- Medicines Australia
- Code of Conduct
- Complaints and Appeals Process
- Where to find assistance
- Abbreviations and terms used in this document
- Code of Conduct Committee meetings dates
- Code of Conduct and Appeals Committee membership
- Lodging a complaint – Non-industry Complainant (for example the Therapeutic Goods Administration, a healthcare professional or member of the general public)
- Appeals

Medicines Australia

Medicines Australia is the national association representing the innovative prescription medicines industry in Australia.

Member Companies represent over 85 per cent of the prescription market, and are engaged in the research, development, manufacture, marketing and export of prescription medicines.

Information on Medicines Australia and a list of member companies can be found on the Medicines Australia website at: <http://medicinesaustralia.com.au/about-us/our-members/>

Code of Conduct

The Code of Conduct sets out standards of conduct for the activities of companies when engaged in the marketing of prescription products used under medical supervision as permitted by Australian legislation.

Medicines Australia's Code of Conduct for advertising and promotion of pharmaceutical products has been internationally recognised for its effectiveness in regulating these activities.

The Code of Conduct Committee, with medical, legal and consumer representatives, has the power to direct withdrawal of advertising, require corrective letters or advertisements and impose company fines, for breaches of the Code.

A free copy of the Code of Conduct can be obtained by phoning Medicines Australia on 02 6122 8500.

The Code of Conduct and Code of Conduct Guidelines are available from the Medicines Australia website at:

<http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>

Complaints and Appeals Process

Rights

The rights of pharmaceutical companies, healthcare professionals and members of the general public are recognised, including the right to lodge a complaint and the right to an impartial decision. Where anonymity by a healthcare professional or member of the general public to the pharmaceutical company has been requested, this will be respected. However, anonymous complaints to the Secretariat will not be accepted.

The complaints process is free of charge.

Complainants and the Subject Company have the right to appeal a decision of the Code of Conduct Committee. The appeals process is free of charge for non-industry appellants; however a pharmaceutical company must lodge an appeal bond of \$20,000 when lodging an appeal.

Complaints and appeals will be considered in a transparent, equitable, objective and unbiased manner by the Code of Conduct and Appeals Committees. The complaints handling process will reflect the principles of natural justice and procedural fairness.

Accessibility

The complaints process is readily accessible to pharmaceutical companies, healthcare professionals and members of the general public. An 'Independent Facilitator' is available to assist Non-industry Complainants. Detailed information on the process is included in this document.

Where a complaint falls outside the jurisdiction of Medicines Australia the matter will be referred to the most appropriate alternate body.

Timeframe

The complaints handling process will be responsive and target times for handling complaints are set down in the provisions of the Code of Conduct. The Complainant and Subject Company will be informed of all decisions and provided with an extract of the minutes pertaining to their particular complaint.

Reports

The outcomes of all finalised complaints are published on the Medicines Australia website in quarterly and annual reports.

Code of Conduct Meeting dates

A full list of Code of Conduct meeting dates and cut-off dates for submission of complaints can be found at www.medicinesaustralia.com.au/code-of-conduct/code-and-monitoring-meeting-dates/

Where to find assistance

If you need any assistance understanding the complaints process or the Code, you can contact Medicines Australia on 02 6122 8500 or via email at secretarycodecommittee@medicinesaustralia.com.au

If you would like to discuss your complaint or require assistance in lodging your complaint you will be put in contact with an independent facilitator. There is no cost to access the services of the independent facilitator. The independent facilitators have experience in consumer interests, pharmacology, the pharmaceutical industry and the Code of Conduct. The independent facilitators work as consultants to Medicines Australia.

The 'Code of Conduct Guidelines' is a separate publication that will enhance a reader's understanding and application of the requirements of the Code.

The Code of Conduct and Guidelines are available from the Medicines Australia website at: <http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>

Abbreviations and Terms used in this Document

Abbreviation/Term	
ACCC	Australian Competition and Consumer Commission
AGPN	Australian General Practice Network
AMA	Australian Medical Association
ASCEPT	Australasian Society of Clinical Experimental Pharmacologists and Toxicologists
CHF	Consumers Health Forum of Australia
Company	Means all companies supplying prescription medicines in Australia
Complainant	Means a person or company who lodges a complaint with Medicines Australia under the Code of Conduct
Industry Complainant	Means a pharmaceutical company who lodges a complaint with Medicines Australia under the Code of Conduct
Member Company	Means a pharmaceutical company who is a member of Medicines Australia who lodges a complaint with Medicines Australia under the Code of Conduct
Non-industry Complainant	Means a Complainant who is not a pharmaceutical company (for example a healthcare professional or member of the general public)
Non-member Company	Means a pharmaceutical company who is not a member of Medicines Australia
Product Information	Means a document registered with the TGA which includes information such as the brand name, ingredients, manufacturers name, use and indications for the medicine, contraindications, precautions, adverse reactions and interactions, dosage and administration
RACP	Royal Australasian College of Physicians
RACGP	Royal Australian College of General Practitioners
Subject Company	Means a pharmaceutical company against whom a complaint has been made
TGA	Therapeutic Goods Administration – organisation responsible for the regulation of medicines in Australia

Code of Conduct and Appeals Committee Membership

Code of Conduct Committee	Appeals Committee
Chairman - Independent trade practices lawyer	Chairman - Independent trade practices lawyer
1 consumer nominated by CHF (plus a second consumer if a complaint relates to an activity directed to consumers)	1 consumer nominated by CHF (plus a second consumer if a complaint relates to an activity directed to consumers)
1 general practitioner nominated by the AMA	1 general practitioner nominated by the AMA, RACGP or AGPN
1 general practitioner nominated by AGPN	
1 general practitioner nominated by the RACGP	
1 specialist/physician nominated by the RACP	1 specialist/physician nominated by a relevant College or Society (for example if the complaint was in relation to a treatment for heart disease the Cardiac Society would be requested to find a specialist with no conflict of interest)
1 pharmacologist/toxicologist nominated by ASCEPT	1 pharmacologist/toxicologist nominated by ASCEPT
1 person nominated by the TGA (observer)	
Max. 5 Member Company representatives	Max. 3 Member Company representatives

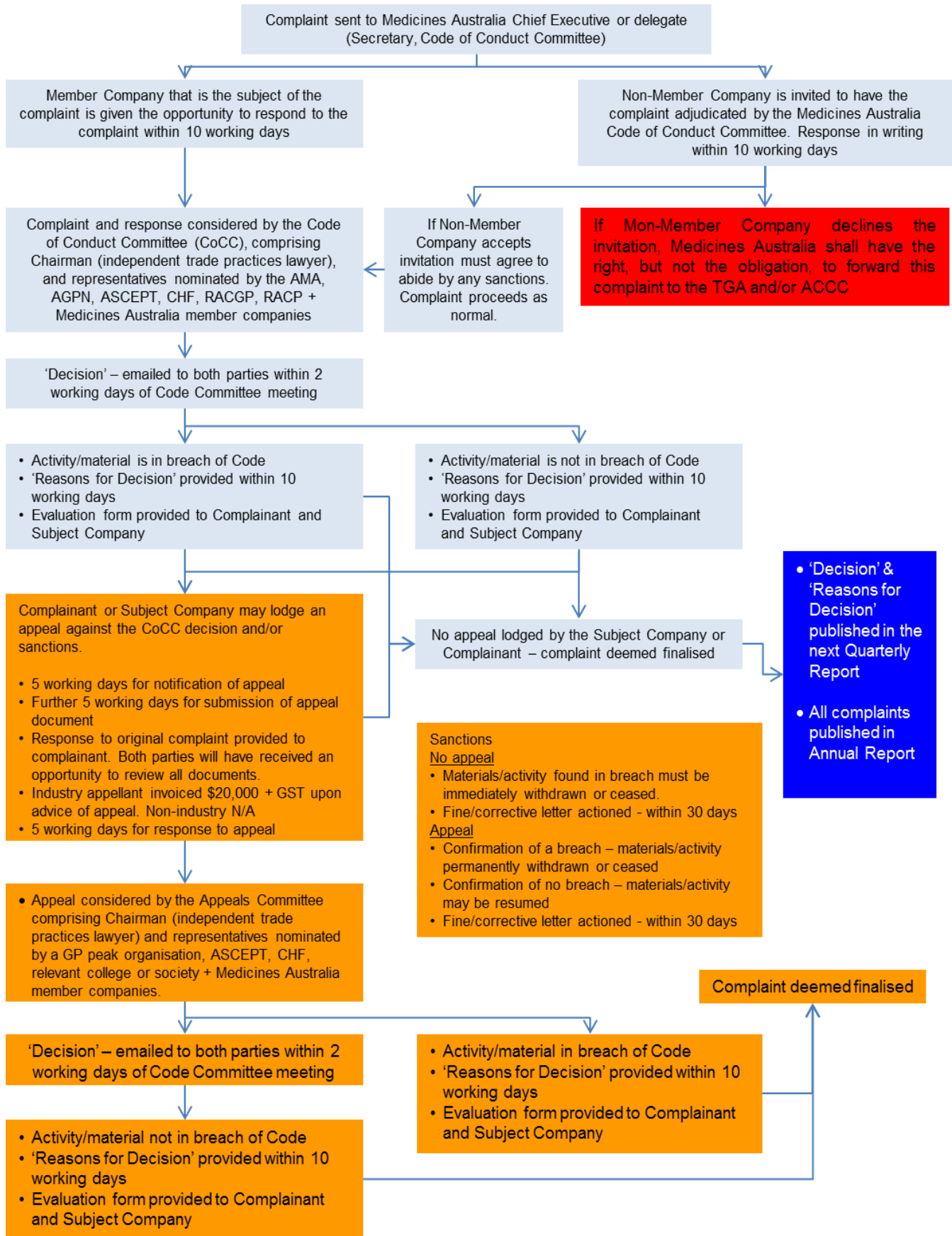
A member of the Code of Conduct or Appeals Committee must not have a conflict of interest with the Complainant, Subject Company or therapeutic area subject to complaint.

No member of the Code of Conduct Committee that heard a particular complaint may participate in the Appeals Committee meeting considering that matter.

Information on members of the Committees can be found on the Medicines Australia website at:

<http://medicinesaustralia.com.au/code-of-conduct/committee-membership/>

Complaints and Appeals Process Summary



Lodging a complaint

A Non-industry Complainant (member of the general public, healthcare professional, academic, Therapeutic Goods Administration) may lodge a complaint in relation to the activities of, or materials developed by, the Australian manufacturer/sponsor of a prescription medicine. There is no cost to lodge a complaint with Medicines Australia.

The preferred method of lodging of a non-industry complaint is by submitting the 'Complaints Submission Form for Non-industry Complainants', which is available on the Medicines Australia website: <http://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/>

The form can be lodged electronically, mailed or faxed to Medicines Australia.

If you do not wish to lodge the 'Complaints Submission Form for Non-industry Complainants', a written complaint can be lodged via email, fax or letter.

Anonymous complaints will not be accepted. However, on request of the complainant, the Code Secretariat will withhold your name from the company against whom you are complaining (known as the Subject Company). Medicines Australia will not publish the name of a Non-industry Complainant in any reports on the outcomes of code complaints.

Independent Facilitator

When enquiring about lodging a complaint you may ask for assistance in this process. An 'Independent Facilitator' is available to assist in formulating the complaint and identifying sections of the Code that may be relevant to the complaint. This service (maximum 2 hours) will be provided free of charge to a Non-industry Complainant.

Medicines Australia has three independent facilitators. You will be referred to the person with the expertise most relevant to your complaint. All facilitators have an understanding of the Code of Conduct and the complaints process.

Facilitator expertise:

- Experience in medicines, e-health, privacy national policy and advocacy and on behalf of health consumers and carers.
- Experience in the relationships between consumer health organisations and the pharmaceutical industry; a broad understanding of issues in the public and private health sectors, a sound understanding of the Australian National Medicines Policy and the pharmaceutical industry.
- Experience in medical writing and communication and pharmacology

Do I need to contact the pharmaceutical company before I lodge a complaint?

It is not mandatory for a Non-industry Complainant to contact the pharmaceutical company about whom you are complaining and discuss your concerns, however this is encouraged. The independent facilitator can assist you by contacting the pharmaceutical company on your behalf to discuss the

complaint and seek an explanation. If you are not satisfied with this response the facilitator can assist in formalising the complaint before you send it to Medicines Australia.

What should be submitted?

Complaints Submission Form for Non-industry Complainants – downloadable from the website: <http://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/>.

What information should be in my complaint?

The complaint (whether via form, letter, fax or email) should, where possible, include the following:

- Name of the company responsible for providing the information or undertaking the activity alleged to be in breach of the Code;
- Brand name of the medicine (if known);
- Approved name of the medicine (if known);
- Where the information appeared (for example a journal, magazine, newspaper or television)
- Date of publication/broadcast or activity;
- A copy of the material (where possible);
- Description of the matters believed to be in breach of the Code - identifying specific issues, claims or activities;
- Particular sections of the Code alleged to be in breach. An Independent Facilitator may assist you to identify relevant sections of the Code. If a complaint is received by Medicines Australia and no sections of the Code have been identified you will be offered the assistance of a facilitator to assist in this process. If declined Medicines Australia will identify relevant sections of the Code against which the Subject Company must respond.
- Where the complaint is based on medical or scientific issues, evidence to support the complaint is desirable but not mandatory;
- Details of any attempts to resolve matter;
- Name and contact details; and
- If you are not lodging the 'Complaints Submission Form for Non-industry Complainants' please include the following information:
 - If you do not wish to have your name and contact details provided to the pharmaceutical company
 - If you wish to use the services of an 'Independent Facilitator'
 - Declaration of any conflict of interest

Where do I send my complaint?

Complaints should be sent to the Chief Executive of Medicines Australia or the Secretary of the Code of Conduct Committee.

Postal Address	Phone	Fax	Email
Level 1 16 Napier Close DEAKIN ACT 2600	02 6122 8500	02 6122 8555	secretarycodecommittee@medicinesaustralia.com.au

Who do I contact if I require assistance?

Secretary of the Code of Conduct Committee – contact details above.

Medicines Australia will try to assist you and can offer you the service of an independent facilitator. See above for further information on the independent facilitators.

What happens after the Code of Conduct Committee meeting?

- You will be provided with a brief statement of the decision within 2 working days
- You will be provided with the 'reasons for the decision' within 10 working days
- A report on each finalised complaint is included in the Code of Conduct Quarterly and Annual Reports.

Appeals

Who can lodge an appeal?

An appeal may be lodged by either the Complainant or Subject Company.

Appeals Committee Membership

For a list of members of the Appeals Committee please refer to page 7.

Appeals Committee Meetings

Dates for appeals meetings will be determined following consultation with the Code of Conduct Appeals Committee members, the Complainant and the Subject Company. All appeals meetings will be held at an independent meeting venue in Sydney.

In addition to providing written submissions to the Appeals Committee, the Complainant and Subject Company will be provided with the opportunity to make a 20 minute oral presentation to the Appeals Committee. A data projector will be provided for use by the Complainant and Subject Company.

Who can attend an Appeals Committee Meeting?

- The Complainant and Subject Company are permitted to be in attendance at the Appeals Committee meeting to hear the presentations.
- Following questions from members of the Appeals Committee, the Complainant and Subject Company representatives retire from the meeting to allow the Committee to deliberate on the matters before them.

Lodging an appeal

- Written advice of an appeal must be received by Medicines Australia within five (5) working days of receipt of the Code of Conduct Committee reasons for decision.
- The appeal document must be lodged within a further five (5) working days.
- There is no cost for a non-industry appellant to lodge an appeal.
- The written appeal submission will be provided to the other party to the complaint
- A written response to the appeal submission must be provided within five (5) working days. Should this party choose not to lodge a written submission they still have the opportunity to attend the Appeals Committee meeting and make an oral submission.
- The written response to the appeal submission will be provided to the other party

What information should be in my appeal?

You should identify why the Code of Conduct Committee erred in their decision.

You are not required to resubmit materials included in the original complaint and response.

What information will the Appeals Committee review?

Medicines Australia will provide members of the Appeals Committee with copies of the following documents:

- Promotional item/s or material subject to the complaint
- Product Information relevant to the product
- Complaint
- Response to the complaint
- Reasons for the decision from the Code of Conduct Committee meeting pertaining to this matter
- Appeal document/s
- Response to appeal document/s

Where do I send my appeal?

Appeal submissions should be sent to the Secretary of the Code of Conduct Committee.

Postal Address	Phone	Fax	Email
Level 1 16 Napier Close DEAKIN ACT 2600	02 6122 8500	02 6122 8555	secretarycodecommittee@medicinesaustralia.com.au

What happens after the appeal?

- You will be provided with a brief statement of the decision within 2 working days
- You will be provided with the 'reasons for the decision' within 10 working days
- A report on each finalised complaint is included in the Code of Conduct Quarterly and Annual Reports.