

Medicines Australia Code of Conduct lodging and responding to a complaint – Pharmaceutical Company

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

The document also includes advice for pharmaceutical companies on responding to Code of Conduct complaints.

We have tried to make it as comprehensive, accurate and up to date as possible.

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 – Pharmaceutical Company
- 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.

Download a free copy of the Code [here](#).

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

The 'Code of Conduct Toolkit' is a resource to enhance a reader's understanding and application of the requirements of the Code. The Code of Conduct Toolkit is available from the Medicines Australia website at: <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/code-resource-toolkit/>

Abbreviations and Terms used in this Document

Abbreviation/Term	
ACC	Australian Competition and Consumer Commission
AGPN	Australia General Practice Network
AMA	Australian Medical Association
ASCEPT	Australian Society of Clinical Experimental Pharmacologists and Toxicologists
CHF	Consumer Health Forum Australia
Company	Means all companies supplying prescription medicines in Australia
Complaint	Means a person or company who lodges a complaint with Medicines Australia under the Code of Conduct
Industry Complaint	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 Complaint	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/>

Selection and Appointment of Member Company Representatives to the Code of Conduct Committee

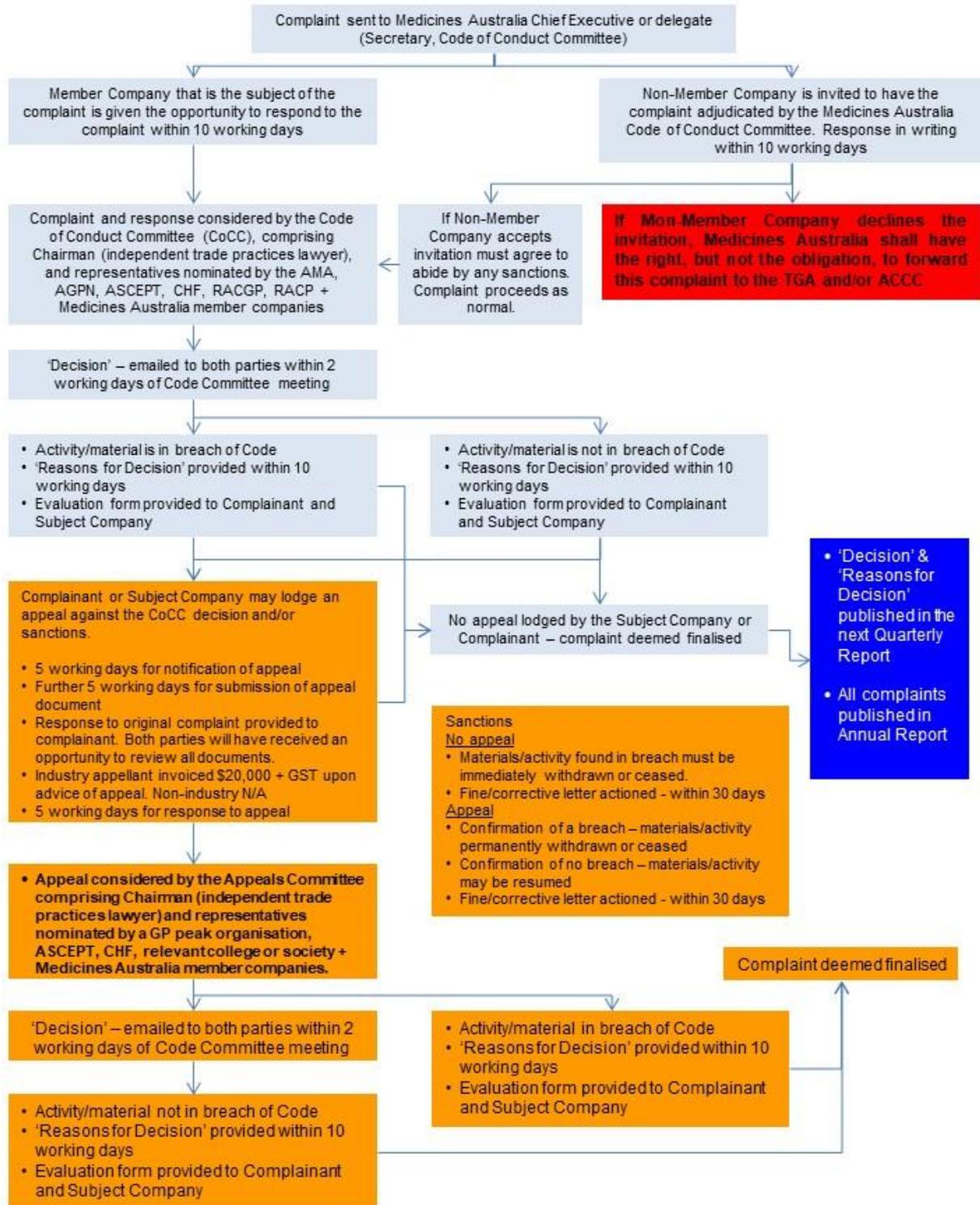
To assist Medicines Australia in determining possible conflicts of interest when selecting Member Company representatives for the Code of Conduct Committee, both the Industry Complainant and Subject Company are requested to answer the following questions when submitting and responding to a complaint.

In addition to any direct or indirect pecuniary interest in a matter about to be considered in a meeting of the Code of Conduct Committee, a conflict of interest may also be considered where a reasonable third party would conclude that there was a likelihood that a participant at the meeting may be influenced in reaching a decision by factors other than the merits of the case as presented by the Subject Company and Complainant.

“Which companies would it **not** be appropriate to have adjudicate on this complaint”:

- Product in the same therapeutic class
- Complaint in another therapeutic area
- Pre-market interest in the same therapeutic class

Complaint and Appeals Process Summary



Lodging a complaint

Intercompany Dialogue

Medicines Australia will not accept a complaint from a company unless it has been clearly demonstrated that intercompany dialogue has taken place and that, despite every effort on the part of both the Complainant and the Subject Company, resolution of the matter has not been achievable.

There must also be evidence of the active involvement of the Company Managing Director in attempting to resolve the complaint. There is no requirement for the Managing Director to participate in teleconferences or face to face meetings, but it should be evident in the complaint materials that he or she has been actively involved in the inter-company dialogue.

Medicines Australia will not accept a complaint from a company where there is no endorsement by the Association Representative, Alternate Association Representative or, in the case of a non-member company, the Managing Director or head of the prescription medicines division. This endorsement is one form of evidence that that Managing Director is fully aware of the complaint being forwarded to Medicines Australia. A company Managing Director may devolve responsibility for complaints to a senior member of the management team, for example the Medical Director, when they are unavailable or out of the country. Advice to this effect should be provided to the other party in any complaint and to Medicines Australia.

What should be submitted?

The following checklist should be used by companies when submitting a complaint to Medicines Australia. Companies should ensure that they have included sufficient detail in their complaint to assist the members of the Code of Conduct Committee in making their decision:

- Executive summary – summary of the complaint including sections of the Code alleged to be in breach;
- Detailed description of the complaint itemising specific claims in relation to each item of promotional material (please refer to items of promotional material by the alphanumeric identifier included at the end of the mandatory text, which specifically identifies the particular item or advertisement) and identifying the particular sections of the Code alleged to be in breach;
- State the nature of the practice being complained about with a clear explanation of the reasons to support the allegation of a breach of the Code;
- Where the complaint is based on medical or scientific issues, supporting evidence is desirable;
- Supporting data should be cross referenced to specific claims alleged to be in breach and a rationale for each allegation;
- Where medical literature is cited, a copy of the literature must be included in the documentation;

- Alleged consequences of the material or activity on healthcare professionals and/or consumers with supporting data or evidence, if available;
- Details of intercompany dialogue/attempts to resolve matter, including minutes of any meeting (whether in person or by teleconference); and Medicines Australia Code of Conduct Complaints Process – information for pharmaceutical companies 9
- All complaints must contain the written endorsement of the Association Representative, Alternate Association Representative or, in the case of a non-member company, the Managing Director or head of the prescription medicines division.

How should the complaint be submitted?

- 20 collated sets of the complaint (each set should be complete)
- Double-hole punched. Do not triple-hole punch materials.
- Clip each set together – no need to include in a file or folder
- Please avoid using plastic sleeves where possible. It is suitable to only to use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

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 via email to secretarycodecommittee@medicinesaustralia.com.au or via mail to 17 Denison Street, Deakin ACT 2606.

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.

Withdrawal of Complaints

While Medicines Australia encourages companies involved in an intercompany complaint to pursue all opportunities to resolve the matter before it reaches the Code of Conduct Committee meeting, the Committee has requested that Medicines Australia provide the following advice to companies in relation to the withdrawal of complaints. This advice is provided following several late withdrawals of complaints following distribution of the meeting agenda papers to the Code Committee.

Under the current provisions of the Code, the response from the Subject Company must be provided to Medicines Australia within 10 working days of receipt of the complaint notification.

If companies are directed to, or wish to continue intercompany dialogue after the submission of a complaint to Medicines Australia, and this action results in a decision by the Complainant to withdraw the complaint, notification must be provided to Medicines Australia by **midday on the Tuesday prior to the Code of Conduct Committee meeting.**

Resolution of Complaint through Intercompany Dialogue

Intercompany Dialogue Guidelines

The purpose of the guidelines is to promote successful intercompany dialogue between companies and provide an official timeframe for companies to undertake dialogue. These guidelines apply to both members of Medicines Australia and non-Medicines Australia member companies.

Dialogue between both the Subject Company and the Complainant should be meaningful with a willingness from both companies to consider each others' position and concerns.

Medicines Australia will not accept a complaint from a company unless it has been clearly demonstrated that intercompany dialogue has taken place and that, despite every effort on the part of both the Complainant and the subject companies, resolution of the matter has not been achievable. There must also be evidence of the active involvement of Company Managing Directors in attempting to resolve the complaint. Medicines Australia will not accept a complaint from a company where there is no endorsement by the Association Representative, Alternate Association Representative or in the case of a non-member company the Managing Director or head of the prescription medicines division. This endorsement is one form of evidence that that Managing Director is fully aware of the complaint being forwarded to Medicines Australia.

Resolution following dialogue

At the conclusion of intercompany dialogue, companies should have clearly documented the position of each party, i.e. including offers made by the subject company to resolve the matter and whether or not the Complainant Company is willing to accept such offers. There should also be clear evidence of any corrective action undertaken by the Subject Company as a result of the intercompany dialogue. Should the Complainant Company still wish to forward the matter to Medicines Australia, the complaint should be accompanied by the consensus minutes and any subsequent correspondence relating to offers to resolve the matter and any actions taken.

Responding to a complaint – Pharmaceutical Company

How should the response be submitted?

Electronically to secretarycodecommittee@medicinesaustralia.com.au **OR** hard copy to 17 Denison Street, Deakin, ACT 2606:

- 20 collated sets in a 2-ring binder/folder (when determining the folder size please consider the size of the complaint which will be inserted behind Tab 3 in your folder)
- Please avoid using plastic sleeves where possible. It is suitable to only use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

Folders must be submitted to Medicines Australia in the following format:

Section 1 (Tab 1): Promotional material subject to complaint Original copies of each item of promotional material or advertisement etc alleged to be in breach of the Code. If original copies are not available, good quality colour photocopies may be provided in the actual size of the original materials (not photo-reduced or enlarged)

Section 2 (Tab 2): Copy of the Product Information Copy of current approved Product Information for the product(s) subject to the complaint

Section 3 (Tab 3): Complaint An original copy of the complaint will be inserted into the complaint response folder by the Code Secretariat prior to distribution to members of the Code of Conduct Committee.

Section 4 (Tab 4): Subject Company response. All information pertaining to the response (excluding the promotional material and the Product Information which are included in their respective sections) must be included behind Tab 4. All supporting documents are to be included in this tab, and appear immediately after the response submission. It is recommended that each article and/or document is identified by a stick-on flag or similar.

Responses should include the following:

- Executive summary;
- Response to each alleged breach raised by the Complainant;
- Where the complaint is based on medical or scientific issues, supporting evidence to rebut the complaint is desirable. If the supporting documentation (for example, an article from the published literature) has already been provided by the Complainant there is no requirement to submit another copy of the reference or study. If you wish to refer to a specific section of the study please identify the study by using the Complainant's appendix or reference number and specify the page and paragraph number;
- Supporting data should be cross referenced to specific claims alleged to be in breach and rationale for defence; Medicines Australia Code of Conduct Complaints Process – information for pharmaceutical companies 13

- Details of intercompany dialogue/attempts to resolve matter. If you are in agreement with the Complainant's recital of the intercompany dialogue please note this in your submission, but do not include another copy of this documentation;
- Evidence of early involvement of the Managing Director in any complaint should be provided; and
- All responses must contain the written endorsement of the Association Representative, Alternate Association Representative or in the case of a non-member company the Managing Director or head of the prescription medicines division.

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 6.s

Appeals Committee Meetings

Dates for appeals meetings will be determined following consultation with the Code of Conduct Appeals Committee, 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.

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.
- Notification of an appeal by an industry appellant must be accompanied by a bond of \$20,000.
- There is no bond for a non-industry appellant.
- The written appeal submission will be provided to the other party to the complaint for their response
- 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 will be provided to the other party for information

What information should be in my appeal?

- The appeal submission should identify why the Code of Conduct Committee erred in their decision. Medicines Australia Code of Conduct Complaints Process – information for pharmaceutical companies 15
- Neither the Complainant nor Subject Company need resubmit materials included in the original complaint and response.
- The Appeals Committee shall have the discretion to receive new evidence (being evidence which was available but not presented to the Code of Conduct Committee).

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 materials subject to complaint
- Product Information
- 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

How should the appeal be submitted?

Electronically to secretarycodecommittee@medicinesaustralia.com.au **OR** hard copy to 17 Denison Street, Deakin, ACT 2606:

- 10 collated copies of all appeal documents from an industry appellant
- Double-hole punched. Do not triple-hole punch materials.
- Clip each set together – no need to include in a file as the documents will be added to the Code of Conduct complaint folder by the Code Secretariat (see above).
- Please avoid using plastic sleeves wherever possible. It is suitable to only use plastic sleeves on materials that cannot be hole punched (e.g. thick detail aid or small leave behind)

What happens after the Appeals 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.