

How to Make a Complaint - Guidelines for Non-Industry Complainants

KEY PRINCIPLES

The complaints process is:

- **Accessible** - it is free of charge, and an 'Independent Facilitator' is available to assist non-industry complainants.
- **Responsive** - target times for handling complaints are articulated in the Code, with meeting dates published on the Medicines Australia website here.
- **Transparent** - outcomes of complaints are published on the Medicines Australia website here.



The purpose of these Guidelines is to inform healthcare professionals, various stakeholders and members of the general public who are considering lodging a complaint under the Medicines Australia Code of Conduct.

ABOUT THE CODE OF CONDUCT

Medicines Australia's Code of Conduct sets the standards for the ethical marketing and promotion of prescription pharmaceutical products in Australia, and provides a principles-based framework for appropriate and ethical decision making. It is underpinned by the Therapeutic Goods Regulations and the Therapeutic Goods Act.

The Code of Conduct, which was established in 1960, has been revised on a regular basis, with the current Edition 20 being available on Medicines Australia website. The Code of Conduct has been internationally recognised for its effectiveness in regulating the marketing and promotion of prescription medicines.

Adherence to the Code of Conduct is a requirement of membership of Medicines Australia. The TGA states that, as a condition of registration, prescription medicines must be promoted in accordance with this Code of Conduct, whether the Company is a member or non-member.

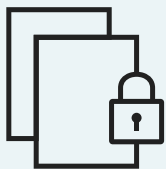
Pharmaceutical companies, healthcare professionals and members of the general public have the right to lodge a complaint if they believe the Code has been breached, and the right to an impartial decision.

THE CODE AND APPEALS COMMITTEE

Complaints and appeals will be considered in a transparent, equitable, objective and unbiased manner by the Code of Conduct and Appeals Committees. These Committees are governed by the Code of Conduct and independent of Medicines Australia.

Each Member Company must conform to and be bound by the Code of Conduct, including submitting to the complaints handling process. The process reflects the principles of natural justice and procedural fairness.

These Committees provide a robust and independent mechanism to hear and manage complaints made under the Code of Conduct. An explanation of the role of these Committees, along with their membership, is available on the Medicines Australia [website](#).



Where anonymity by a healthcare professional or member of the general public to the pharmaceutical company has been requested, this will be respected.

In all circumstances, Medicines Australia will not publish the name of a non-industry Complainant in any reports on the outcomes of code complaints. However, anonymous complaints to the Secretariat will not be accepted.

HOW TO LODGE A COMPLAINT

Email the Code Secretariat via codehelpdesk@medicinesaustralia.com.au, or call 02 6147 6500 if you wish to lodge a complaint in another format.

It is important that any complaint is accompanied by enough information to allow the complaints handling process to proceed. Please use the checklist, located as an appendix to this Guidance.

How to get assistance in making a complaint

If you need any assistance understanding the complaints process or the Code, you can contact the Code Secretariat. 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. This service (to a maximum of 2 hours) will be provided free of charge.

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, and you will be referred to the person with the expertise most relevant to your complaint.



It is not mandatory 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 I expect after my complaint is lodged?

The complaints handling process, which is articulated in the Code of Conduct at Section 15, will be followed. A summary flowchart detailing the process is located as an appendix to this Guidance.

The Code Secretariat will acknowledge your complaint within 5 working days of receipt. The Code Committee will hear the complaint, the date in accordance with the [published meeting dates](#).

After the Code of Conduct Committee meeting, you will be provided with a brief statement of the decision within 2 working days, and a more detailed 'reasons for the decision' within 10 working days.

After this, a report on the complaint will be published on the [Medicines Australia website](#). This will take place within one month of the finalisation of the complaint, noting that Medicines Australia will not publish the name of a non-industry complainant in any reports on the outcomes of code complaints.

APPEALING A DECISION

If you are not happy with the decision made by the Code Committee, you may lodge an appeal. Similarly, if the Subject Company is not happy with the decision, they may also lodge an appeal. The cost to appeal is free if you are a non-industry complainant. If you decide to appeal, you need to give written notice within five working days of receiving the decision(s) and reason(s) of the Code Committee.

Consistent with the process of the Code Committee, an Appeal Committee hears any appeal. The date for an appeal meeting will be determined following consultation with the Appeals Committee members, the Complainant and the Subject Company.

An appeal is a rehearing of the part of the original complaint that is subject to the appeal. The Appeals Committee has the power to affirm, set aside or vary the findings and/or any sanction which has been imposed by the Code Committee. The Appeals Committee shall have the discretion to receive fresh evidence (being evidence which has become available after the complaint was considered by the Code Committee), however there are limitations to decision-making in an Appeal situation. Further detail as to how an appeal is heard, and what information can be considered with an appeal is found in Section 15 of the Code of Conduct.

How do I lodge an appeal?

Notify the Code Secretariat of your intention to lodge an appeal by sending an email to codehelpdesk@medicinesaustralia.com.au. This notice needs to be provided within 5 working days of receiving the decision(s) and reason(s) of the Code Committee.

You then have a further 5 working days to email through written submissions that support your appeal. It is important that any appeal is accompanied by enough information to allow the complaints handling process to proceed.

Please use the checklist located as an appendix to this Guidance.



The Complainant and Subject Company will be provided with the opportunity to make a short presentation to the Appeals Committee, and both parties are permitted 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.

What should I expect after my appeal has been lodged?

The Code Secretariat will acknowledge your appeal within 5 working days of receipt.

Any written appeal will be provided to the other party, which will then have the opportunity to make a written response to the appeal. The other party has 10 working days to submit such a response. The written appeal submission and responses received will then be provided to the Appeals Committee for their review, and a date for the Appeals Committee is established.

After the Appeals Committee meeting, you will be provided with a brief statement of the decision within 2 working days, and a more detailed 'reasons for the decision' within 10 working days. After this, a report on the complaint and appeal will be published on the [Medicines Australia website here](#). This will take place within one month of the finalisation of the appeal, noting that Medicines Australia will not publish the name of a non-industry complainant in any reports on the outcomes of code complaints or appeals.

IF IN DOUBT, REACH OUT

- Download Edition 20 of the Code of Conduct from our [website](#)
- SCAN THE QR CODE to send an email to the [Code Help Desk](#)



COMPLAINTS AND APPEALS PROCESS

Complaint sent to Medicines Australia

Electronic submission by 5pm on the cut-off date.



MEMBER COMPANY

Subject company is provided 10 working days to respond to the complaint



NON-MEMBER COMPANY

Invited to have the matter heard by Medicines Australia, agree to comply with process

If the Non-Member Company declines invitation, complaint may be sent to the TGA and/or ACCC

Complaint and response considered by the Code of Conduct Committee

- Meetings usually scheduled for the 3rd Monday of every month
- Material/Activities found in breach must be immediately withdrawn or ceased



Decision emailed to both parties within 2 working days of the hearing



Full reasons for decision provided within 10 working days of the hearing

Either party may appeal the decision or sanctions handed down by the Committee

APPEAL

NO APPEAL

Complaint is Final



Intent to appeal lodged within 5 working days of receipt of reasons



Appellant has a further 5 working days provided to make an appeal submission



The non-appellant party has 10 working days to make a response

Appeal and response considered by the Appeals Committee



Decision emailed to both parties within 2 working days of the hearing



Full reasons for decision provided within 10 working days of the hearing

Complaint considered final

- Fines are payable within 30 days of receipt of invoice
- Corrective action completed within 30 working days of receipt of Committee approved template
- Outcomes of Complaints published on the Medicines Australia [website](#) within 30 working days



INFORMATION CHECKLIST



This is a checklist for information that needs to be provided when making a complaint. You can use the help of an Independent Facilitator to gather or present this information.

- Name of advertiser / sponsor responsible for providing the information
- Brand name of medicine
- Approved name of the medicine

If your complaint relates to an advertisement or any promotional material:

- Where the advertisement or promotional material appeared (name of journal, magazine, newspaper, TV, radio, webinar, internet, social media, outdoor display etc)
- Date published or date observed
- Please provide a copy of the advertisement, to the best of your ability. This could be a screen recording, a screenshot, a photo, a scanned copy, or any other means. If the medium is difficult to record, such as TV, please identify the channel of station and an approximate time of broadcast (eg Channel A on Sunday evening 13 July 2021)

If your complaint relates to an activity, or conduct of a pharmaceutical representative:

- Relevant information on the activity
- Date and place observed

The nature of your complaint:

- Please state what your complaint is, including, where possible, the section of the Medicines Australia Code of Conduct breached
- Please provide details of any communication you have had with the advertiser or sponsor company
- Please advise if you are aware of any legal action in relation to this material. If so, please give details

Your information:

- Name
- Contact details including email address, mobile phone number and postal address
- Please advise if you do not wish your name and contact details to be given to the other party/sponsor company, and your rationale