

Guidelines for Industry Generated Complaints

KEY PRINCIPLES

The Medicines Australia complaints process is:

- **Independent and fair** - through following a documented process heard by the Code and Appeals Committee, all parties will receive fair and equitable treatment.
- **Responsive** - target times for handling complaints are articulated in the Code, with meeting dates published on the [Medicines Australia website](#).
- **Transparent** - outcomes of complaints are published on the [Medicines Australia website](#).



The purpose of these Guidelines is to provide responsive timeframes and explain the complaints handling process, should a pharmaceutical company wish to lodge a complaint with Medicines Australia. If the principles in these Guidelines are not met, the complaint may be returned for more information, or the review may be conducted in the absence of a complete response.

MAKING A COMPLAINT

Medicines Australia is committed to the fair and ethical administration of the Code of Conduct, including the provision of a robust and independent complaint and appeal process. This ensures that all parties are entitled to fair and equitable treatment.

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 by the Complainant and the Subject Company, resolution of the matter has not been achieved.


Medicines Australia will not accept a complaint from a company where there has not been endorsement by the Senior Executive Officer (generally described as Managing Director, Chief Executive Officer, General Manager, Regional Director or otherwise). If the Senior Executive Officer is unable to engage in the matter, evidence of delegating authority to the company Medical Director must be submitted along with the complaint.

Intercompany Complaints should not be used as a competitive tool.

PROCEDURES FOR INTERCOMPANY DIALOGUE

Companies will first seek to resolve all complaints through discussions between both parties. The Complainant and Subject Company are both encouraged to initiate dialogue at any point in the process.

If inter-company dialogue criteria is not met, any ensuing complaint may be returned for more information. These procedures may only be altered by mutual agreement of both parties. Dialogue can take many forms, not limited to face-to-face. Digital platforms may be utilised, however an exchange of letters will not usually be considered sufficient.



Intercompany dialogue is a vital component of the complaint process, applying to members of Medicines Australia and non-Medicines Australia member companies. Dialogue between the Subject Company and the Complainant should be meaningful, with a willingness from both companies to consider each other's concerns and with the intention of resolution.



Responding to a formal complaint

Subject Company must respond to any issues raised by the Complainant within 10 working days

Next steps

After the Subject Company has responded, the parties must organise a meeting* to discuss any unresolved issues within 10 working days

Can't agree to a meeting?

In that case, direct contact between two company senior executive officers must occur and meeting* organised within 2 working days

*Remember, this meeting must occur before a complaint can be sent to Medicines Australia

After the meeting



The parties have 5 working days to finalise consensus minutes and agreed outcomes from the meeting. The record of this meeting must be submitted to Medicines Australia with the complaint should it proceed.

If it is agreed that further intercompany dialogue is required, this must be undertaken within a further 10 working days

Resolution following Intercompany Dialogue

If, at the end of the intercompany dialogue process, all complaints have been resolved the matter is considered closed. There should be clearly documented evidence to support the position of each party, detailing agreements or corrections accepted.

Where complaints remain unresolved and a complaint is submitted to Medicines Australia, all correspondence including offers for resolution and actions taken should be included in the complaint material. This evidence may contribute to a reduction in sanction should one be imposed, or require the Complainant to justify actions in submitting a complaint.

Withdrawal of complaints

If companies are directed to, or wish to continue intercompany dialogue after the acceptance of a complaint and this action results in a decision by the Complainant to withdraw the complaint, notification must be provided to Medicines Australia by 5pm on the Monday prior to the next scheduled Code Committee meeting.

Limitation on complaints

Complaints will not be accepted by Medicines Australia where the promotional material or activity occurred in a period of time greater than 24 months from lodgement of the complaint, unless the material or activity remain in force at the time of lodgement.

MAKING A COMPLAINT

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. The Complaint should include the following information:

EXECUTIVE SUMMARY	A summary of the complaint, including the Overarching Principles and Sections of the Code that are alleged to be in breach
DETAILED COMPLAINT	<p>Itemisation of specific claims in relation to each item of promotional material / activity, and identifying specific sections of the Code that are alleged to be in breach.</p> <p>A sufficiently detailed complaint is one that:</p> <ul style="list-style-type: none"> • clearly identifies promotional material using the item's unique identifier (located with the mandatory promotional information) • clearly states the nature of the practice being complained about with an explanation of the reasons to support the allegation of a breach of the Code. • outlines the alleged consequences of the material or activity on healthcare professionals and/or consumers (with supporting evidence if available.) • includes evidence to support claims that are based on medical or scientific issues • includes a copy of medical literature cited in the complaint • cross references specific claims to supporting data and includes a rationale for each allegation
INTERCOMPANY DIALOGUE	Details of intercompany dialogue, and attempts to resolve the matter, including minutes of all meetings. Complainants should articulate outstanding items requiring the Code Committee's adjudication.
ENDORSEMENT	All complaints must contain the written endorsement of the senior executive officer.

How to submit your complaint

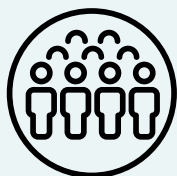
Once you have all of the information collated, please email your complaint, along with all of your supporting information, to the Medicines Australia Code Secretariat. Email codehelpdesk@medicinesaustralia.com.au or phone (02) 6147 6500.

Hard copies of complaints are not required.

What to expect after a complaint is submitted

The Medicines Australia Code Secretariat will acknowledge receipt of your complaint within 5 working days, and process the complaint as expediently as possible and in accordance to the timeframes indicated on page 7 of this Guidance.

After your complaint is acknowledged, Medicines Australia will provide a copy of the complaint to the Subject Company for their response. The complaint will be heard by the Code Committee in accordance with the dates published on the Medicines Australia website.



Confidentiality and Conflict of Interest are taken seriously by the Code Secretariat. Information on 'Who's Who' on the Code and Appeal Committees, and also their selection process, is on the [Medicines Australia website](#). Complainants and Subject Companies are also welcome to identify competitor companies that should not be party to the complaint hearing.

Repeat Breach

In the case of an alleged repeat breach, renewal of intercompany dialogue is encouraged but not necessary, and complaints may be automatically submitted to Medicines Australia. If the activity does not fall into the definition of 'repeat breach' or new activities are introduced, Medicines Australia will not accept the complaint. In this case, intercompany dialogue must be renewed.

Double Jeopardy

Medicines Australia will not accept a complaint if the subject matter has already been substantially dealt with by the Code Committee. That is, if the particular section or sections of the Code in relation to the same activity or same material irrespective of whether there was a finding of a breach of the Code. In these circumstances, the Complainant will be referred to the outcomes of the previous complaint.

If the complaint is alleging a breach of a different section of the Code, or a matter related to revised materials, this will be considered a new complaint. Similarly, material that or activity that was found in breach but not withdrawn or ceased will be considered a new complaint.

Withdrawal of a complaint

Medicines Australia encourages companies to pursue all opportunities to resolve the matter before it reaches the Code of Conduct Committee meeting. 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 1 week prior to the Code of Conduct Committee meeting.

RESPONDING TO A COMPLAINT

When a complaint has been accepted by Medicines Australia, the Subject Company is asked to state whether or not the information supporting the complaint is correct, and to give any answer or explanation which may be deemed necessary.

Companies should ensure that they have included sufficient detail in their response to assist the Code Committee in making their decision. When providing this information, the Subject Company should include:

EXECUTIVE SUMMARY	A summary of the response to the Complaint
DETAILED RESPONSE TO THE COMPLAINT	<p>Itemisation of responses to specific claims made in the complaint in relation to each item of promotional material / activity.</p> <p>A sufficiently detailed response to the complaint is one that:</p> <ul style="list-style-type: none">• includes original copies of promotional material discussed in the Complaint clearly responds to the specific claims made in the complaint with an explanation of the reasons to support the activity.• includes evidence to support claims that are based on medical or scientific issues• includes a copy of medical literature cited in the complaint and access to the approved Australian Product Information document• cross references specific claims to supporting data and includes a rationale for defence of each allegation
INTERCOMPANY DIALOGUE	<p>Details of intercompany dialogue, and attempts to resolve the matter, including minutes of all meetings. If the Subject Companies is in agreement with the Complainants recital of the intercompany dialogue, it should be noted in the submission, and another copy is not required in the response documentation.</p> <p>Where consensus minutes were not agreed upon, the Subject Company should also enclose their recording of the meeting.</p>
ENDORSEMENT	All complaints must contain the written endorsement of the senior executive officer.

Abuse of the Code

If a concern is raised that the complaint is frivolous or vexatious, before the Code Committee considers the matter it will request the Complainant to provide its response to the allegation, including any reasoning why the Committee should not impose a maximum fine of \$200,000 for abuse of the Code of Conduct. The Complainant must provide a response to this request within 10 working days for consideration at the next available Code Committee meeting.

APPEALING A DECISION

If you disagree with the decision made by the Code Committee, you may lodge an appeal. Similarly, if the Subject Company disagrees with the decision, they may also lodge an appeal. Notification of an appeal by an industry appellant must be accompanied by a bond of \$20,000. 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 Appeals 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 original complaint. 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.



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.

How to lodge an appeal

Email the Medicines Australia Code Secretariat of your intention to lodge an appeal via codehelpdesk@medicinesaustralia.com.au. This written 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.

What should I expect after an appeal has been lodged?

The Code Secretariat will acknowledge appeals 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 within one month of the finalisation of the appeal.

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 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

IF IN DOUBT, REACH OUT

- Download Edition 19 of the Code of Conduct from our [website](#)
- SCAN THE QR CODE to send an email to the [Code Help Desk](#)

