

Guidelines for Industry Generated Complaints

KEY PRINCIPLES

The Medicines Australia complaints process is:

- **Independent and fair** - A structured and documented process ensures complaints are adjudicated by the Code and Appeals Committees, providing all parties with fair and equitable treatment.
- **Responsive** - The Code outlines timelines for handling complaints, with Committee meeting dates published on the [Medicines Australia website](#).
- **Transparent** - Complaint Outcomes are published on the [Medicines Australia website](#), ensuring accountability and openness in the process



These Guidelines explain the complaints process and provide responsive timeframes if a pharmaceutical company wants 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 of the complaint may be conducted in the absence of a complete response.

MAKING A COMPLAINT

With the implementation of Code Edition 20, new Intercompany Dialogue Standards ('ICD Standards') have been adopted and are available on the [Code Resource Toolkit](#). Before accepting a complaint from a company, Medicines Australia requires clear demonstration that intercompany dialogue has taken place and the complaint has not been resolved to the satisfaction of both parties.

The ICD Standards recognise that in some cases companies might not be able to agree on the ICD outcomes (see 'Outcomes not Agreed'). The complainant may submit the complaint to Medicines Australia as described in the ICD Standards.

The ICD Standards require that the Managing Director or Medical Director of both the Complainant Company and Subject Company sign the ICD record. Medicines Australia will not accept a complaint if the required signatures are not provided. If the complainant company's Managing Director is unable to engage in the matter, documented delegation of authority to a senior executive must accompany the complaint.

Refer to the ICD Standards for details on complaint submission and acceptance.

PROCEDURES FOR INTERCOMPANY DIALOGUE

Companies must attempt to resolve complaints through intercompany dialogue. The ICD Standards outline the required procedures and expected timeframes for each stage of the process. The ICD Standards are intentionally detailed and specific so that both parties to the complaint have clear expectations. Any variation from the ICD Standards may only occur with mutual agreement from both parties.

Failure to follow ICD Standards (Code Section 15.5)

Code Edition 20 introduced a new provision whereby either the Complainant or Subject Company may allege that the ICD Standards were not appropriately followed by the other company. If the allegation of a breach of Section 15.5 is made by the Complainant Company in its complaint, the Subject Company should respond to this allegation as part of its response to the complaint.

If it is alleged by the Subject Company that the Complainant Company has breached Section 15.5, the Code Committee will consider the allegation and may, but is not obliged to, request a response from the relevant company (see Complaints Alleging a Breach of Section 15.5 in the ICD Standards). The response must be provided to Medicines Australia within 10 working days and will be considered at the next or a future Code Committee meeting.

These processes provide procedural fairness so that a company will have the opportunity to respond to an allegation of a breach of Section 15.5 before any finding of breach is made by the Code Committee. The Code Committee may issue a fine of up to \$100,000 for a confirmed breach of Section 15.5 of the Code.



Intercompany dialogue is an essential component of the complaint process, applying to members of Medicines Australia members and non-member companies. Dialogue following the ICD Standards should give confidence to both companies there is a consistent, robust process that demonstrates their shared intention to resolve matters where possible.

The ICD Standards state that in most cases Medicines Australia will accept a complaint and refer it to the Code Committee for adjudication. However, in specific circumstances outlined in the ICD Standards (see Medicines Australia's Acceptance of Complaints), Medicines Australia is not obligated to accept a complaint. Acceptance of a complaint does not imply an assessment of its validity, any change to its scope during ICD or whether reasonable efforts were made by either company to resolve the issue/s.

When submitting a complaint to Medicines Australia, all correspondence, including resolution offers and actions taken, should be documented as outlined in the ICD Standards. This evidence may influence the outcome, potentially reducing sanctions imposed by the Code or Appeals Committee or requiring the Complainant Company to justify the complaint under Section 15.4 Frivolous or Vexatious Complaints (see next page).

Refer to the ICD Standards for details on complaint withdrawals and limitations on acceptance.

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. A Complainant has the burden of proving their complaint on the balance of probabilities.

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), or includes a copy of the material subject to the complaint• 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	The ICD record, including details of all communications and records of meetings and attempts to resolve the matter. Complainants should articulate the outcomes of ICD and unresolved 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 gathered all the required information, submit your complaint along with supporting information, to the Medicines Australia Code Secretariat via email at codehelpdesk@medicinesaustralia.com.au or contact (02) 6147 6500 for assistance. Hard copies of complaints are not required.

What to expect after a complaint is submitted

The Medicines Australia Code Secretariat will process the complaint as expediently as possible and in accordance with the timeframes summarised on page 8 of this Guidance. After Medicines Australia acknowledges receipt of your complaint, they 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.

Repeat of a previous Breach

For alleged repeat breaches, renewing intercompany dialogue is encouraged but not required, and complaints may be submitted directly to Medicines Australia. If the activity does not fall within the definition of 'repeat of a previous breach', and instead new activities or alleged breaches are introduced, Medicines Australia will only accept the complaint after new intercompany dialogue has occurred.

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 same section or sections of the Code are alleged to have been breached 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 concerns a matter related to revised materials, this will be considered a new complaint. Similarly, a complaint about material or activity that was found in breach but not withdrawn or ceased will be considered a new complaint (refer to Section 15.6 c)).

Withdrawal of complaints - see ICD Standards

Limitation on acceptance of complaints - see ICD Standards



Confidentiality and Conflict of Interest are taken seriously.

Information on 'Who's Who' on the Code and Appeals Committees, and also their selection process, is on the [Medicines Australia website](#).

Companies are welcome to identify competitor companies that should not participate in the complaint adjudication due to conflicting interests.

Frivolous or Vexatious Complaints

Complaints should not be used as a competitive tool. If the allegation of a breach of Section 15.4 is made by the Complainant Company in its complaint, the Subject Company should respond to this allegation as part of its response to the complaint.

If it is alleged by the Subject Company that the Complainant Company has breached Section 15.4 and the complaint is frivolous and/or vexatious, the Code Committee will consider the allegation and may, but is not obliged to, request a response from the Complainant company. The response must be provided to Medicines Australia within 10 working days and will be considered at the next or a future Code Committee meeting.

These processes provide procedural fairness so that a company will have the opportunity to respond to an allegation of a breach of Section 15.4 before any finding of breach is made by the Code Committee. The Code Committee may issue a fine of up to \$100,000 for a confirmed breach of Section 15.4 of the Code.

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.

This response is the primary opportunity for a company to outline their position; they are not afforded further opportunities unless the outcome is appealed. Therefore, 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>If the Subject Company agrees with the ICD record submitted by the Complainant it should be noted in the response to the complaint and another copy is not required in the response documentation.</p> <p>Where the Subject Company disagrees with any aspect of the ICD record, this should be explained and detailed in the response to the complaint</p>
ENDORSEMENT	All complaints must contain the written endorsement of the senior executive officer.

Complaints against Non-member Companies (Section 15.3)

Non-member companies are invited to have any complaint about their conduct adjudicated by the Code Committee. If the non-member company accepts this invitation, the complaint will be forwarded to the Code Committee. If the non-member declines this invitation, Medicines Australia has the right, but not the obligation, to forward the complaint to the TGA or the Australian Competition and Consumer Commission.

If the complaint alleges that promotional materials or activity are in breach of the Code, and the non-member company has declined to have the matter adjudicated by the independent Code Committee, Medicines Australia may refer the complaint to the TGA to adjudicate on whether there has been a breach of that condition of registration for that related product.

The complaint would be submitted to the Regulatory Compliance Branch. The matter will be referred to the appropriate area within the TGA for assessment.



It is a condition of product registration on the Australian Register for Therapeutic Goods (the ARTG) that promotional activities, including promotional materials, for that prescription product comply with the Medicines Australia Code of Conduct.

Information submitted to the TGA is held in strict confidence. The TGA does not release information to the public or complainants about its compliance and enforcement activities, unless required by the investigative process or deemed in the public interest. In such cases, compliance actions, outcomes and infringement notices are published [on their website](#).

There is no defined timeframe for managing a complaint referred to the TGA by Medicines Australia. The TGA will follow its existing process as outlined in the [TGA Regulatory Compliance Framework](#). In deciding on a course of action, the TGA will generally consider:

- the seriousness of the alleged non-compliance and failure to follow the regulatory requirements
- the risk of harm or injury related to a product itself, including the way in which a product is used or being promoted for use
- the indirect risk of harm from reliance on misleading or inaccurate information
- the compliance history and behaviour of the responsible person or business
- the level of compliance of the particular industry sector.

The TGA is unlikely to refer complaints back to Medicines Australia for consideration by the Code Committee. However, in an appropriate case the TGA may consult with Medicines Australia on technical matters to assist it with its investigations.

APPEALING A DECISION

Either the Subject Company or the Complainant Company may lodge an appeal if they disagree with the decision made by the Code Committee. Notification of an appeal by any industry appellant must be accompanied by a bond of \$20,000.

The appellant company must give written notice to Medicines Australia of its appeal within five working days of receiving the Reasons for Decision of the Code Committee.

How to lodge an appeal

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

The appellant company then has a further 5 working days to email the written submission that support its appeal to the Code Secretariat. 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 Medicines Australia Code Secretariat will process the appeal as expediently as possible and in accordance with the timeframes summarised on page 8 of this Guidance.

After Medicines Australia acknowledges receipt of the appeal, they provide a copy of the appeal to the other complaint party for their response. The other party has 10 working days to submit its response. The written appeal submission and responses received will then be provided to the Appeals Committee which will hear any appeal.

The date for an Appeals Committee meeting will be determined following consultation with the Committee members and both companies involved in the complaint.

An appeal is a rehearing of the part of the original complaint that is the subject of 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 has the discretion to receive fresh evidence (being evidence which has become available after the complaint was considered by the Code Committee). Refer to Code Section 15.7 for further details about an appeal.



In an appeal, each company will be provided with the opportunity to make a short presentation to the Committee, and both companies may hear both presentations. Following questions from Committee members, the company representatives retire from the meeting to allow the Committee to deliberate on the matters before them.

Up to three representatives from each of the companies involved in an appeal may attend the Appeals Committee meeting; this includes any external expert assisting a company.

After the Appeals Committee meeting, both companies will be provided with a brief statement of the decision within 2 working days, and the more detailed 'Reasons for the Decision' within 10 working days. This concludes the appeal process.

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

