

# The Standards for Intercompany Dialogue



These Standards have been developed to support Code Edition 20, which will come into effect 30 March, 2025.

## Preamble

**This document describes the expected Standards for Intercompany Dialogue (Standards), which will promote meaningful communication and interaction between a Complainant Company and Subject Company in relation to a complaint under the Medicines Australia Code of Conduct.**

Dialogue between Companies should be undertaken with a willingness to consider each other's position and concerns, with the intention of achieving an agreed outcome in a timely manner. If an agreed outcome cannot be achieved through Intercompany Dialogue (ICD), it should be clear to both Companies that any unresolved matters may be submitted to Medicines Australia for adjudication by the Code of Conduct Committee. The Standards outline the expected timeframe for Companies to complete the ICD in order to resolve the matter and, if unresolved, to submit a complaint to Medicines Australia.

All interactions between Companies through ICD must be consistent with the Australian Competition and Consumer laws. Member Companies should refer to Medicines Australia's guidelines for discussions between members prior to commencing ICD with another company.

It is intended that Companies will be specific and comprehensive in their written communications – in both the complaint and any response to the complaint.

The Standards describe the formal ICD process once a Formal Written Complaint is made. It does not include informal communications (e.g. e-mail, phone calls) seeking to resolve complaints before starting the formal ICD process. Companies are encouraged to undertake informal communications as a first step, as often these can swiftly resolve concerns, particularly when they are between managing directors or medical directors. All communications, once the ICD process formally starts, should be documented as part of the formal ICD record.

The Standards should give confidence to both Companies for a consistent, robust ICD process that demonstrates an aligned intention to resolve matters where possible.

Intercompany Complaints should not be used as a competitive tool; that is, they should not be used as a mechanism to distract another company from its normal business activities.



## Defining the Scope of a Complaint

**The first written communication is considered the Formal Written Complaint, which will start the formal ICD process and define the scope of the ICD. This will encourage both Companies to be considered, comprehensive and precise and will give certainty about the scope of the ICD and timeframes for each communication, to avoid inappropriate delays and expansion of the scope of a complaint.**

- The Formal Written Complaint must be clearly identified as such (e.g. a formal header “Intercompany Dialogue – Formal Written Complaint”), which will trigger the ICD process.
- The Formal Written Complaint establishes the scope of the ICD and scope of any future complaint that might be submitted to Medicines Australia. It must set forth the full scope of the complaint, including:
  - a. material(s), event(s), and/or activity(ies) subject to the complaint;
  - b. the issue(s) raised; that is, the substance of the complaint;
  - c. citation of Code section/subsection and requirement or principle that is alleged to have been breached; and
  - d. any references or other material that is relied on in making the complaint.
- Any counter-complaint by the Subject Company will initiate a new and distinct complaint (that is, a new Formal Written Complaint) and initiate a separate and distinct ICD process and timeframe
- Amendments to the Formal Written Complaint by the Complainant during formal ICD should not be made, except with the documented, mutual agreement of the Companies. Any amendments should be limited to the materials, events, or activities already described in the Formal Written Complaint. For example, additional examples of materials using the same promotional claim allegedly in breach of the Code might be added to the scope with mutual agreement. However, a different promotional claim within the same or different materials would expand the scope of the existing first Formal Written Complaint and will be deemed a new complaint and subject to a new (and separate) Formal Written Complaint.
- For clarity, any new aspects, elements, or claims in the subject material of the Complaint, or any new materials alleged to be in breach of the Code, not detailed in the first Formal Written Complaint cannot be introduced (unless with documented, mutual agreement of the Companies). It is intended that the Complainant Company should comprehensively describe the full scope of its complaint at the outset.

## ICD Steps and Timeframes

- The Formal Written Complaint sent to the Subject Company starts the ICD process timeframe.
- A written Response to the Complaint from the Subject Company should be received by the Complainant Company within ten (10) working days.
- For the purpose of calculating the number of working days, the timeframe starts on the next business day for each step in the ICD process.
- After receiving the Response to the Complaint, within ten (10) working days, the Complainant and Subject Company must organise a meeting (e.g. face-to-face, teleconference or virtual) to discuss any unresolved issues. For avoidance of doubt, the meeting should be held within ten (10) working days from receipt of the Subject Company's response except with the documented, mutual agreement of the Companies.
- If no date for the meeting has been agreed within ten (10) working days, direct communication between the senior executive officers of the two companies must occur and a meeting must be organised within two (2) working days.
- Finalised minutes of the ICD meeting and outcomes should be agreed by the Complainant and Subject Companies within ten (10) working days of the meeting. These minutes form part of the documentation of ICD that should be submitted with any complaint that is later submitted to Medicines Australia. If the companies are unable to agree on the minutes of the meeting and outcomes within ten (10) working days, each company may submit its own record of the meeting to Medicines Australia (as part of the Complaint or Response to the Complaint). The completion of minutes and statement of agreed outcomes signals the end of the ICD process.
- With the documented, mutual agreement of both Companies, further ICD may occur, but should be undertaken within a further ten (10) working days, which includes agreement on the outcomes of the further ICD. If the complaint is still not resolved within this timeframe, a complaint may be submitted to Medicines Australia.

## Creating a Documented Record

All communications between companies once a Formal Written Complaint is made must be documented if they are to be later considered by the Code Committee, including:

- Written communications, formal and informal (letters or emails); or
- Minutes or transcripts of verbal communications, including informal communications (e.g. telephone calls) and formal ICD meetings (face-to-face or virtual)

At the conclusion of the ICD timeframe, all outcomes must be documented in a clear and concise format which describes both the Complainant Company's and Subject Company's understanding of the outcome. The outcomes could be:

- resolved – either:
  - a) Subject Company accepts there was a breach and remedy or corrective action is agreed; or
  - b) Complainant Company accepts there was no breach; or
  - c) Subject Company does not accept there was a breach, but remedy or corrective action is agreed;
- unresolved – either:
  - a) Subject Company accepts there was a breach but remedy or corrective action was not agreed; or
  - b) Subject Company maintains there was no breach.

## Submitting a Complaint to Medicines Australia

- Only matters that are unresolved may be submitted to Medicines Australia as a complaint. Matters that have been resolved should not be included in the submitted complaint, except for being identified in the ICD documentation. The Code Committee will not adjudicate on any resolved matters included in a complaint relating to unresolved matters. For avoidance of doubt, where the outcome is unresolved only with respect to remedy or corrective action, the Code Committee will only adjudicate on the remedy or corrective action and not the underlying alleged breach.
- The ICD record must be signed by the managing director or medical director of both the Complainant and Subject Company.
- The Complainant must submit any complaint to Medicines Australia within fifteen (15) working days from the conclusion of the ICD process, notwithstanding that the next Code Complaint cut-off date is later. For avoidance of doubt, there is a fifteen working day period after the end of the ICD process to submit a complaint to Medicines Australia. No extension of time will be allowed.

### Outcomes not Agreed

- Whilst it is preferable that companies agree on the ICD outcomes, they might not be able to reach agreement. If one company disagrees with the outcome summary (for example, unresolved in the view of one company and resolved in the view of the other company), the Complainant may submit the complaint to Medicines Australia within fifteen (15) working days, with clear documentation identifying the different positions of each company on the ICD outcomes.

## Timeframe

- ICD must be completed within thirty-five (35) working days commencing from the date of the first Formal Written Complaint.
- An additional ten (10) working days is allowed to continue ICD with mutual agreement.
- Days not considered working days for purposes of calculating the Timeframe:
  - a. Public holidays
  - b. 23 December through 14 January
- Issues that are unresolved may be submitted to Medicines Australia as a complaint within fifteen (15) working days of the conclusion of ICD.
- Timeframes may not be amended except by the documented, mutual agreement of both the Complainant and Subject Company.

## Medicines Australia Acceptance of Complaints

**In a majority of cases, a complaint that is submitted to Medicines Australia will be accepted and referred to the Code of Conduct Committee for adjudication.**

Medicines Australia is not obligated to accept a complaint if one or more of the following are evident:

- No ICD has occurred between the Complainant Company and Subject Company;
- There has been no ICD meeting between the Companies
- There is no evidence of Managing Director engagement for both parties (i.e. MD not present at an ICD meeting and/or no MD signature on correspondence between the parties);
- 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 remained in force at the time of lodgement.
- The Complaint is submitted more than fifteen (15) working days after the conclusion of ICD as described in the ICD steps and timeframes above.

Medicines Australia's acceptance of a complaint does not extend to assessing whether:

- The content of the complaint is valid
- Either company made a reasonable effort to resolve the complaint
- There has been a change to the scope of a complaint from the first Formal Written Complaint to when it is submitted.

These matters should be argued to the Code of Conduct Committee by the Complainant Company or Subject Company in the complaint or response to the complaint under the Failure to Follow Intercompany Dialogue Standards provisions of the Code (*Section 15.5*).

## Complaints Alleging a Breach of Section 15.5

If a breach of *Section 15.5* is alleged as one part of a complaint submitted to Medicines Australia or in the response to a complaint, the Code Committee may request the relevant company to provide its response to this concern in accordance with that Code Section.

If an alleged breach of *Section 15.5* is the only complaint submitted to Medicines Australia (that is, all other matters discussed during intercompany dialogue were resolved or not otherwise submitted to Medicines Australia as a complaint), it will be handled as a new complaint in accordance with *Section 15.2* Complaints Process and Handling. The Complaint must be submitted within fifteen (15) working days after the conclusion of ICD, as described in the ICD steps and timeframes above.

An allegation that the ICD Standards have been breached does not require continuation or reinitiation of intercompany dialogue between the Companies on this matter. This includes whether the alleged breach is made as one part of a complaint submitted to Medicines Australia or where the complaint of a breach of *Section 15.5* is the only matter submitted to Medicines Australia.

## Withdrawal of complaints

If Companies are directed to, or wish to continue ICD 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.

\*Working day "clock" starts on the next business day for each

