

NFTHD #96: Do Non-Member Pharma Companies Need to Follow the ICD Standards?

In this Notes from the Help Desk, we explore the practical question of whether pharmaceutical companies that are not members of Medicines Australia are bound to follow the Inter-Company Dialogue (ICD) Standards. These Standards, referenced in the Code of Conduct, are designed to ensure companies engage in structured, responsive and meaningful dialogue before escalating issues to a formal complaint. While they provide the roadmap for quality ICD, their application to non-member companies is less straightforward.

Complaints and ICD

For any company - member or non-member - wishing to lodge a complaint with Medicines Australia, there is an expectation that ICD has first taken place (Section 15.1c). In practice, this means the ICD Standards serve as the roadmap for how dialogue should occur, even though there is no strict requirement for non-member companies to follow them.

Standards vs. Requirements

The ICD Standards focus on the quality and system of ICD, rather than the mere fact that dialogue occurred. If a complaint progresses to Medicines Australia and ICD was not conducted in line with the Standards, the responding subject company could raise a counter-complaint that the complainant company did not follow the ICD Standards (alleged breach of Clause 15.5).

Here, things get interesting: under Section 15.3, a non-member company (in this scenario the complainant), will be invited to have that counter-complaint heard by the Code Committee. If they accept, they effectively become accountable to the Standards. If they decline - but still pursue their original complaint - it is likely the Code Committee would still proceed with considering the complaint on its merits, while retaining the flexibility to assess the situation at face value and apply the principles of fairness that underpin the Code. As this scenario has not yet occurred, it is difficult to say categorically how it would play out in practice.

Sentiment and Practical Reality

The prevailing sentiment is that if a company chooses to use the complaints process, it should also accept being subject to counter-complaints. This principle applies to both members and non-members, though there is no current formal instrument mandating it.

For member companies, compliance with the ICD Standards is essential. If a non-member does not engage with the process outlined in the Standards, the onus is on the member company to demonstrate that they made every effort to follow the Standards. This generally provides a strong defence against any allegation of a breach of Section 15.5, and also feeds into the overall consideration of the Code Committee if they are to set any sanctions (see [NFTHD#94](#) for principles on sanction setting).

Bottom Line

Non-member companies are not formally bound to the ICD Standards. However, once they engage with the Medicines Australia complaints process, the Standards become the framework by which dialogue is assessed. In practice, they shape expectations for all parties - members and non-members alike - ensuring fairness, accountability, and quality in inter-company dialogue.

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