

NFTHD #94: Sanction setting - principles

In this Notes from the Help Desk, we outline the key principles and factors that the Code of Conduct and Appeals Committees consider when determining sanctions under the Code.

What is a sanction?

A sanction can be imposed on a company that has been found to be in breach of the Code. Sanctions may take one or more of the following forms:

- Ceasing the activity and withdrawing any materials found to be in breach (the minimum sanction where applicable); and/or
- Issuing a corrective letter or advertisement; and/or
- Paying a monetary fine.

Purpose of sanctions

The ultimate purpose of sanctions is to serve as an accountability mechanism — not only to deter breaches, but to uphold confidence in the Code and maintain trust in the industry. The Code is both meaningful and enforceable, which is why it is respected by regulators and our overseas counterparts, and held in high regard by other industries. Beyond this, sanctions also serve to:

- Ensure false or misleading materials are withdrawn and not reused,
- Correct inaccurate or misleading information, where appropriate,
- Protect public health and safety by ensuring accurate information is shared.

Principles for determining sanctions

When the Code of Conduct or Appeals Committees impose a sanction, the process is guided by clear principles to ensure consistency, and fairness:

- 1. Transparency:** Both the complainant and the subject company should be able to understand the basis on which sanctions are applied. This is made known in the Reasons for Decision and also assisted by the publishing of these principles.
- 2. Consistency with flexibility:** Sanctions should be predictable and consistent, but not rigid or static. This balance ensures fairness while allowing Committees discretion to consider each case's unique circumstances. To support this principle, the Chair is provided with an overview of previous similar complaints and sanctions to help steward the Committee in achieving consistency of decisions.
- 3. Proportionality:** Sanctions are applied as a package to ensure the overall outcome is proportionate. For example, where corrective action such as issuing a corrective letter is required, the Committee may determine that a lower fine is appropriate to balance the total sanction.

Decision-making for monetary sanctions

The Code sets the maximum monetary fines for each breach category (minor, moderate, or severe), which are reviewed during each Code review. When a breach is determined, the Committee first assesses its severity using the Code definitions. From there, they consider whether a fine is appropriate, and if so, the range (low, mid, or high) within that category. In making this decision, the Committee takes into account factors such as:

- **Nature and extent of the activity or material** – how misleading, damaging, or disparaging the activity or material was, and also, whether the breach should have been evident to the subject company.
- **Breadth and length of the activity or campaign** – how widely the materials were distributed or promoted and how long the materials were in circulation.
- **Number and type of breaches** – whether it involves a single breach or multiple breaches of different kinds.
- **Context of the activity** – including circumstances and any explanation provided by the company.

Other considerations

The Committee can also look at a company's past behaviour and attitude - for example, whether the breach went against its own rules or training, if the company admitted the breach, what steps it has taken to prevent it happening again, how cooperative it has been, and whether there is a pattern of repeat breaches.

Some breaches will naturally attract higher sanctions because of their seriousness - particularly where patient safety is at risk, or where the breach undermines confidence in the pharmaceutical industry as a whole.

Finally, it is worth noting that beyond financial penalties, reputational damage can be one of the most significant consequences for a company. Through its decisions, the independent Code of Conduct Committee plays a critical role in ensuring accountability and promoting ongoing compliance across the industry. Because complaint outcomes and reasons are published transparently, companies may face the very real impact of negative headlines or the need to issue a mea-culpa to healthcare professionals. For many companies, reputational impact may in fact be the most significant consequence - one that should not be underestimated. The Committee remains mindful of this in its deliberations.

Sanction setting is not an exact science - every case has its own circumstances and complexities. However, the process is firmly guided by clear principles that ensure fairness, proportionality, and consistency across Committee meetings.

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