

NFTHD #4: Interpreting a principles-based Code

Code Edition 20 takes a principles-based approach to ethical decision-making. But what does 'principles-based' mean and why and when did this shift historically occur?

The Code of Conduct was first launched in 1960, when Medicines Australia was known as the Australian Pharmaceutical Manufacturers Association (or APMA). The early editions of the Code are comprised of high level provisions that set the tone for the acceptance and adoption of high ethical standards in the Australian pharmaceutical industry. It is the genesis of widely understood expectations on making claims about therapeutic goods and the birth of our mantra: 'fair, balanced, accurate, and correct.'

Over time, however, societal expectations changed and so too did the Code. It grew to reflect the needs of members in ensuring personnel could interpret the Therapeutic Goods Act adequately and behave appropriately. At the launch of Edition 18 in 2015, the Code had grown 98 pages of heavily detailed provisions and a 200 page guideline document that were a long way from the early editions. Members agreed that, as an industry, we should be held to high standards but that such prescriptiveness could inhibit engagement with new technology and didn't support the information needs of our audiences. So, after a lengthy review process, the Code of Conduct Edition 19 returned to its roots: high level principles that empowers risk-based decision making and accountability rather than 'tick-a-box compliance'. The 20th Edition of the Code builds on this foundation and maintains a principles-led approach.

Edition 20 opens with a set of Overarching Principles. These principles are not new, they are not revolutionary. These principles have been the backbone of industry's ethical conduct since that first edition in 1960. They are front and centre, supporting Companies in navigating the promotion of therapeutic products and engaging with stakeholders. But a principles-based Code does not mean that there are no details or specifics! There are still mandatories, expectations, and requirements which are set out in the Sections of the Code.

Applying the Code principles is simple in theory but may be difficult in practice. It decentralises the ownership of ethical behaviour decisions beyond just Compliance teams, moving away from checklists and templates towards conversations and interpretation. The Code is a tool to help industry rise up to meet the information needs of our audiences, in an appropriate and ethical way. A lack of guidance in the Code doesn't automatically prohibit an activity, rather it is permission to explore how or if it meets those Overarching Principles.

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