Consultation Paper

An Invitation to Contribute to a Review of Medicines Australia's Code of Conduct Edition 19

Introduction

Medicines Australia is undertaking a review of its Code of Conduct ("Code").

The current Code, Edition 19, came into effect in March 2020. It demonstrated a significant shift from the previous rules-based, detailed, and prescriptive Code Edition 18 to a new streamlined, principles-based approach. The Code Guidelines that supported Code Edition 18 were also retired and replaced by the Code Resource Toolkit which provides a range of subject-specific resources to guide Code implementation.

It was intended that Code Edition 19 would:

- be easier to read, understand, and share with stakeholders;
- encourage and empower companies to make ethical decisions without the need for prescriptive "rules"; and
- be "systems-neutral"; that is, designed to apply to different systems and technologies as they change, and as new technologies are adopted.

Now that Code Edition 19 has been in effect for four years, it is timely to evaluate whether these goals have been met and whether refinement is needed.

The review will apply a diversity of thinking and views to ensure that the Code is representative of real-world experiences and current technologies while continuing to maintain our industry's reputation as being of the highest ethical standard.

Objectives and Expectations

Medicines Australia has set the following objectives for this Code Review:

To review the Principles and Sections in the Code, with the aim of:

- *ensuring the Code remains relevant in light of the changing roles and practices of the wider industry and the patient and professional community;*
- *continuing to align with international self-regulation and domestic policies, legislation, standards, other regulatory norms, and community expectations;*
- *clarifying any requirements where experience with the Code suggests there may be ambiguity; and*
- *updating guidance and resources in line with these objectives.*

Medicines Australia will undertake this review in an open and consultative manner and welcomes all comments from member companies and other stakeholders with an interest in the Code.

This Code review will build on, rather than replace, the work undertaken during the development of Code Edition 19. The shift towards a principles-based Code has been welcomed by Medicines Australia member companies and the wider stakeholder community. There is no intention to change from the principles-based approach and supporting clauses, found in Code Edition 19. The review is an

opportunity to evaluate how Edition 19 has been implemented and make improvements where identified.

If an amendment to an Overarching Principle (found in Part A) or another clause is found to be needed, or a new clause is required to close a "gap", it should:

- reduce or eliminate ambiguity;
- be "systems-neutral" to future-proof the Code;
- avoid adding unnecessary detail and thereby reverting towards a more prescriptive Code; and
- avoid wordsmithing unless it is essential for better interpretation, clarity, or accuracy

There is also no intention to change the requirements for transparency of interactions with healthcare professionals and with consumers described in Part E of Code Edition 19. Transparency and public reporting of these interactions have been in place in Australia for almost a decade and are consistent with similar transparency requirements for the pharmaceutical industry in many other countries. However, the Code review is open to any input that might improve on these requirements in Code Edition 19.

The current compliance assurance mechanisms described in Part F of Code Edition 19 – Code Governance will not fundamentally change. However, if these processes can be improved upon, the review will consider any suggestions from stakeholders.

Review Timeframe and Methodology

Consultation with Medicines Australia members and a wide range of stakeholders will commence at the beginning of April 2024, signaled by the publication of this Consultation Paper.

Medicines Australia has established a Code Review Working Group (CRWG) comprising nominees, representing a broad base of expertise, from its member companies. The CRWG will review all comments and inputs to the review.

During the Code review, the CRWG plans to hold two workshops with member companies to discuss any proposed changes to the Code. The first workshop will be held in mid-July 2024, once all comments have been received and the CRWG has analysed the input and developed its recommended changes. The CRWG will take the feedback received from the workshop and refine its recommendations, which will then be presented to and discussed with members at a second workshop in late August 2024. The CRWG will finalise its recommendations based on members' feedback.

The CRWG will recommend changes to the Code to the Board of Medicines Australia and, if endorsed by the Board, a revised Code Edition 20 will be proposed for adoption at the Medicines Australia Annual General Meeting in October 2024. If adopted, Code Edition 20 will become effective in March 2025.

Key Topics for Consideration

The CRWG highlighted several topics on which it would welcome comments from members and other stakeholders. **Please note that these are not the only topics that will be considered as part of the Code review**. They are based on CRWG members' own experience with Code Edition 19, discussions within the Code Compliance Network across member companies, matters raised by complaints made under Code Edition 19, and questions raised through the Code Helpdesk at Medicines Australia.

These are topics where member companies and stakeholders are likely to have a view and are worthy of discussion. They **may** indicate that the Code could be improved in some areas, but at the start of the review, the CRWG does not propose a specific position or amendment to the Code. Rather, it wishes to hear from stakeholders. All stakeholders are encouraged to comment on these topics **and any other topics that you would like considered by the CRWG,** including any gaps or ambiguities that should be addressed by an addition to the current Code or Code guidance.

1. **New technologies for communication with healthcare professionals**

Code Edition 19 was implemented immediately prior to the COVID-19 pandemic. In designing Edition 19, not only was there a significant change in moving away from a prescriptive to a principles-based Code it was also intended to modernise the Code to be much less focused on traditional print-based media, reflecting the increasing utilisation of new media and modern communication channels. The COVID pandemic necessitated even more rapid adoption and utilisation of new communication channels between pharmaceutical companies and healthcare professionals.

Has Code Edition 19 gone far enough to leave behind the legacy provisions of previous Code editions that were primarily designed for print media? Can more "systems-neutral" approaches be adopted and reflected in the Code?

One example is the requirement for information about a product – the Product Information (PI) or the Minimum Product Information (MinPI) – to be provided or made accessible whenever a promotional claim is made about a product (Section 2.1). The mechanisms to provide this information refer to printed "material" or "publications" as well as using a "URL or hyperlink for electronically accessed materials". The Code does not refer to the use of a QR code to access the PI, although QR codes are commonly used today in many media for many different purposes to access information. How could the Code be improved to recognise new technologies?

There is a further question about the relevance of the Minimum Product Information (MinPI). The MinPI was originally designed to provide minimum information to enable appropriate prescribing of prescription medicines, recognising the impracticalities of including the "full" PI within an advertisement in print media. Given changes to digital access to information noted above, is the MinPI still useful to prescribers? Considering changes to the format of the Product Information introduced by the Therapeutic Goods Administration (TGA) from 2018 to 2020, does the MinPI continue to have a purpose that is not served by providing access to the PI?

2. **Informing the general public about the availability of new products and new indications**

Code Edition 18 included a section specific to product specific media statements (Section 13.4.1). Consistent with the intention noted above to be much less focused on traditional print-based media and channels of communication, Code Edition 19 takes a principled approach to Ethical Interactions with Patients and the General Public, in Part D of the Code. Section 13.2 covers educational information and disease awareness. Code Edition 19 does not include provisions relating to "product specific media statements". Part D is broader in scope, referring to all forms and channels used to provide educational (non-promotional) information to patients and the general public.

In its reasons for its decisions in Code complaint 1172, which related to a media statement about a new treatment, the Code Committee recommended that "*the upcoming Code Review 2024 consider whether it is appropriate for the Code to include a provision directed to the publication of consumer-focused statements (along the lines of Section 13.4.1 of Edition 18*)". As part of the consideration of complaint

1172, there was discussion of whether Section 11 of Code Edition 19, *Appropriate Communications with Relevant Stakeholders*, was more applicable to the publication of a media statement.

Does Code Edition 19 provide sufficient guidance to companies by taking its more principled approach to providing educational information about medical conditions and treatments? Do Sections 11 and 13 in Code Edition 19 complement each other or are there gaps or overlap that lead to less clarity of interpretation? What are the pros and cons of including a provision about consumer-focused statements in the Code as recommended by the Code Committee? What forms and channels of communication are used currently for communicating and interacting with patients and the general public (websites; social media channels such as LinkedIn, Instagram, Facebook, X, TikTok; public print media), and does Code Edition 19 clearly and adequately address their appropriate use now and for the future? In what ways could the Code be clearer in relation to these materials?

3. <u>Scientific Exchange with healthcare professionals</u>

Section 8 of Code Edition 19 contains provisions relating to the exchange of information between pharmaceutical company personnel and healthcare professionals. It is intended to enable this non-promotional exchange about unregistered products and off-label topics. Point 3 of Section 8 states that only Company Medical Department personnel may engage in such exchange.

After four years' experience with Code Edition 19, does this model for non-promotional scientific exchange continue to be appropriate? Is the concept of "scientific exchange" sufficiently clear to companies to support these non-promotional interactions with healthcare professionals? Is the meaning of a "non-promotional" exchange clear? Does the reference to "Company Medical Department personnel" continue to reflect models of working within pharmaceutical companies? Is there a less prescriptive way of describing the types of roles with the appropriate knowledge and experience that could engage in non-promotional scientific exchange about unregistered products or uses? Does the fifth dot point in Section 8, relating to digital medical information applications, continue to cover the types of digital technology used by companies to make appropriate information accessible to healthcare professionals?

4. <u>Improving Inter-company dialogue in relation to complaints</u>

Part F of Code Edition 19, *Code Governance*, deals with matters relating to lodging a complaint. Section 16.1, *Acceptance of Complaints* requires companies to first seek to resolve all complaints through the inter-company dialogue process described in the Code Tool Kit. The Code states that Medicines Australia will not accept a complaint from a company unless there is clear demonstration that inter-company dialogue has taken place and that, despite the reasonable efforts of the parties, the complaint has not been resolved.

It is not unusual for a complainant company or a subject company to dispute that the inter-company dialogue process was properly undertaken. It might be argued by one company that the inter-company dialogue was ongoing and a complaint should not be accepted by Medicines Australia or argued that one company had not demonstrated reasonable efforts to try and resolve the matter and had delayed the process.

After several issues about inter-company dialogue were raised in complaints in 2023, the Code Committee recommended that "*it would support a decision by Medicines Australia to develop threshold criteria concerning complaint acceptance and inter-company dialogue, enabling companies and committees to understand clearly whether these thresholds have been met, and therefore allowing both parties to fully understand when a complaint may be made*."

Is it appropriate for the Code to refer to the inter-company dialogue process described in the Code Resource Toolkit, or should "threshold criteria" about complaint acceptance and inter-company dialogue be included in Section 16.1? How could the inter-company dialogue process be improved from the perspectives of both parties engaged in a complaint, through amending the Code and/or the relevant *Guidelines for Industry Generated Complaints* in the Code Resource Toolkit?

5. Engaging non-member companies in the Code complaints process

When a prescription medicine is registered in the Australian Register of Therapeutic Goods (ARTG), it is a Condition of Registration that any promotional activities must comply with the Medicines Australia Code. This applies to all companies that supply registered prescription medicines, whether they are a Medicines Australia member or a non-member.

Code Section 16.3 *Complaints against non-members* describes how complaints submitted to Medicines Australia about the conduct of a non-member company will be managed. The non-member will be invited to have the complaint adjudicated by the Code Committee, including agreeing to abide by the Committee's decision and any sanctions imposed. The non-member company may decline this invitation. If a non-member company declines to have a complaint adjudicated by the Code Committee, Medicines Australia may forward the complaint to the TGA or the Australian Competition and Consumer Commission.

If a complaint is submitted about the conduct of a member company, the member is required by the Medicines Australia Constitution to have the complaint adjudicated by the Code Committee and to comply with any decision.

Are there any changes to the Code that would encourage non-member companies to engage in the Code complaints process in the same way as member companies?

One option is non-member agreements such as those under the Association of the British Pharmaceutical Industry (ABPI) Code of Practice. Companies that are not members of the ABPI may give their formal agreement to abide by the Code and accept the jurisdiction of the Authority that administers the Code, the PMCPA, including the adjudication of complaints. Would this system be appropriate in Australia in relation to the Medicines Australia Code? Would non-member companies be interested in exploring this option?

Another option is to discuss revising the Conditions of Registration for prescription medicines with the TGA so that the conditions would require all companies to not only comply with the Code but also accept the Code complaints process and abide by any decisions of the Code Committee. What are the pros and cons of this option?

Are there other options that would encourage non-members to engage in the Code complaints process? Are there other aspects of Section 16.3 that could be improved or clarified?

6. Improving Code guidance resources

When Code Edition 19 was implemented the former "Code Edition 18 Guidelines" document was retired and replaced by the Code Resource Toolkit. The Toolkit provides a range of guidance documents and resources to aid compliance by assisting companies to interpret and apply the Code. There are now more than twenty individual guidance resources available in documents and videos.

The CRWG is aware that it can be difficult to find information within these guidance resources due to their increasing number and variety, particularly if someone is new to the medicines industry. How can the accessibility of these guidance resources be improved? Are there examples from other sectors or

other industries that would be useful in relation to the Code guidance? Could the format of the guidance materials be changed to increase their usefulness to companies when interpreting and applying the Code?

In addition, are there other guidance resources that could be developed that are specific to the Code or, more broadly, related to ethical business practice and compliance?

7. Emerging trends from Australia and internationally

The Code of Conduct is part of an international network of ethical business practice standards. As a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Medicines Australia Code must remain consistent with the IFPMA Code of Practice. The IFPMA is currently reviewing its Code of Practice, which will be finalised in April 2025. IFPMA member associations will have until December 2026 to consider if any changes to their Codes are needed to maintain consistency with the IFPMA Code of Practice. The CRWG will be monitoring the IFPMA Code review and will take any emerging issues into consideration in its work on the Code of Conduct.

More broadly than the IFPMA Code review, the CRWG invites input from stakeholders about emerging trends and changes in business practices in other countries that should be considered for inclusion in the Medicines Australia Code or the Code guidance resources. For example, since Code Edition 19 came into effect in March 2020 the Pharmaceutical Research and Manufacturers of America (PhRMA) updated its Code on Interactions with Health Care Professionals in January 2022 and the Singapore Association of Pharmaceutical Industries (SAPI) updated its Code of Conduct in January 2023. Are there any issues from these or any other country's updated Codes that should be considered as part of this Code review? Are there other emerging trends internationally, or locally (e.g. in other healthcare industry associations or societies) that the CRWG should consider? How are these trends applicable to the Australian context?

How to provide feedback

Responses are invited from all member companies, non-member companies, industry associations, peak healthcare professional organisations, patient groups, and other interested stakeholders. Feedback can be provided as an organisational response, or by individuals.

Responses are encouraged via this **online survey** (https://form.jotform.com/240838729954068) which will remain open until COB, 2 May 2024. Survey responses can be anonymous, if preferred. You may choose to respond to some or all questions, as relevant.

Written feedback can also be emailed to codehelpdesk@medicinesaustralia.com.au, until 2 May 2024. If you choose this option, the below suggestion is provided as a guide to inform your response:

Section of the Code / Key Topic If you know it, identify the main section of the Code your comment applies to	**Feedback** Comment on the issue	**Example** If relevant, give an example that illustrates your feedback.	**Proposed solution** If you want to propose a preferred way forward, please state this here