RACGP
Royal Australian College of General Practitioners

Healthy Profession. Healthy Australia.

6 May 2024

Ms Alison Bleathman
Head of Operations and Company Secretary
Medicines Australia
17 Denison Street
Deakin ACT 2600

By email: codehelpdesk@medicinesaustralia.com.au

Dear Ms Bleathman

RE: Review of Medicines Australia's Code of Conduct Edition 19

The Royal Australian College of General Practitioners (RACGP) welcomes the opportunity to provide a submission to the review of Edition 19 of Medicines Australia's Code of Conduct (the Code).

The RACGP is Australia's largest professional general practice organisation, representing over 40,000 members working in or toward a career in general practice.

We have consulted with our general practitioner (GP) members, who have provided feedback in response to the topics listed in the consultation paper, as well as specific sections of the Code. This feedback is summarised below.

General comments

- The RACGP welcomes this principles-based approach which should be maintained and enhanced.
- The Code is easy to understand and written in plain English.
- There appears to be effective regulation of prescription medicines and the pharmaceutical companies producing them, less regulation of over the counter (OTC) medicines (although still a reasonable level), and no regulation of non-evidence-based products sold at pharmacies.
- Monitoring of the Code seems appropriate, and the makeup of the committees outlined in Section 17 is appropriate.

Key topics for consideration as outlined in the consultation paper

1. New technologies for communication with healthcare professionals

The Code should be written to include all types of communication with healthcare professionals with an emphasis on electronic communication. The current references to traditional print-based media and electronic materials could be expanded to include modern digital communication tools such as social media, podcasts, and webinars. Paper-based communication should be phased out as it is not -possible to keep these current as new information becomes available.

Consideration should be given to frequency of communication to avoid 'spamming' health professionals. Additionally, there should be quick and simple options provided for health professionals to personalise communications in terms of method and frequency. This would include 'opt out' areas as currently required by privacy laws.

The Code could explicitly include and provide guidelines for the use of new technologies such as QR codes, augmented reality for product demonstrations, and virtual reality experiences for educational purposes. These technologies can enhance the accessibility of product information (PI) and minimum product information (MinPI), making it more engaging for healthcare professionals. For patients, incorporation within eScripts is a tangible opportunity. From a primary care usability perspective, the full PI is seldom read or may be skimmed to find a relevant section. MinPI may serve a greater purpose given the time constraints of healthcare providers in general.

The Code could include more explicit guidelines on reporting and disclosing interactions, especially in the digital space where interactions can be more nuanced and varied. This could include virtual meetings, digital educational materials, online advisory boards, and asynchronous messaging. The Code could also acknowledge the rapid uptake of generative artificial intelligence (AI) by consumers and the growing popularity of conversational AI for information retrieval.

No patient statements or anecdotes should be used as part of communication.

The Code should also give consideration for a repository and archive of all materials. This should be in an easy to access manner with clear information of the materials' status.

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

Concerns were raised about a potential move to avoid the rules prohibiting the advertising of prescription medicines and devices.

It is almost impossible to separate 'informing the public' from advertising. Information provided to the public should remain as a response to a query from a member of the public. However, there may be instances where a public health authority (state or federal) determines that sharing information with the public for health promotion purposes is in the public interest and acceptable. In such instances, educational information and disease awareness materials to the general public should be clear and accurate, and accessibility standards should apply and should be free from biases.

3. Scientific exchange with healthcare professionals

The concept of scientific exchange in Section 8 of the Code needs more clarity. The Code includes examples of what is allowed but does not include what is not allowed. The definition of company medical department personnel is also inadequate. References to unregistered products and off label uses are concerning and should be removed.

It is not clear that pharmaceutical companies are adequately transparent about the funds used for scientific exchange. Funds shared with health organisations may remain unreported unlike funds shared with individual health professionals. Any funding exchanges between pharmaceutical companies and health organisations of any type, should be listed in the public domain. Additionally, conflicts of interest must be declared, when organisations and individuals that receive funding use this funding to produce educational content and position statements or guidelines that directly impact on accessibility, knowledge, and usage of the funder's products. This should also be the case with respect to research partnerships.

Funding arrangements should be declared for public speaking events and promotional activity, noting this is sometimes a 'fee for service' arrangement whereby a person is paid a rate depending on the time taken to complete a task.

Regarding publications that sit behind paywalls, the pharmaceutical industry should be encouraged to provide the source content to healthcare professionals.

4. Improving Inter-company dialogue in relation to complaints (referring to Section 16 of the Code)

Section 16.1 – Acceptance of Complaints & 16.2 Complaints Process and Handling

Members noted that anonymous complaints are not accepted, and the burden of proof is on the complainant. This is fundamentally different to how the Australian Health Practitioner Regulation Agency operates its complaints process.

Intercompany dialogue is important. Reference to the threshold criteria should be made in section 16.1 with cross reference to the Code Resource Toolkit for details on guidance on meeting the threshold criteria.

5. Engaging non-member companies in the Code complaints process (Section 16 of the Code)

Section 16.3 – Complaints against non-members

Adopting the Association of the British Pharmaceutical Industry (ABPI) Code of Practice is a practical option, but before adopting this, feedback should be sought from the ABPI about their experience and learnings from this.

Section 16.5 – Sanctions

A severe breach resulting in patient safety implications has a maximum fine of $200,000, which does not seem to be a deterrent of any impact for big pharmaceutical companies.

6. Improving Code guidance resources

The guidance resources are critical. As there are a substantial number available, access to the resources could be improved by having an algorithm to assist the user to navigate to the most relevant resources. AI could be used to support identifying the most appropriate resources for different scenarios.

7. Emerging trends from Australia and internationally

With a shift towards patient-centric healthcare, the Code could expand its guidance on how pharmaceutical companies engage with patients and patient organisations. This includes ensuring that patient interactions are conducted ethically, and that patient privacy is rigorously protected.

As pharmaceutical companies operate on a global scale, the Code could provide guidance on harmonising practices with international standards and regulations. This would help Australian companies ensure consistent ethical practices across different markets, especially in areas like clinical trials, drug marketing, and competitive practices.

Reflecting a global shift towards sustainability, the Code could include guidelines on environmental responsibility and social governance. This would address how pharmaceutical companies should manage their environmental impact and contribute to social welfare, aligning with broader corporate responsibility goals.

Further comments

Section 9 – Market research

Section 9 of the Code does not clearly define market research and who would be involved. Members advise examples would be useful.

Section 12 – Support for health consumer organisations & Section 13 – Interactions with the general public

Members suggested Sections 12 and 13 of the Code be combined as consumers and the public are interchangeable.

Section 14 – Patient support programs

This section fails to address over the counter (OTC) medicines.

The cannabis industry

Members raised concerns about the unregulated cannabis industry – specifically the marketing and opportunism of clinics, which are remunerated according to prescription numbers without proper history taking or collaboration with a patient's regular GP.

Thank you for the opportunity to provide a submission. If you have any questions or comments regarding this submission, please contact Stephan Groombridge, National Manager – eHealth, Quality Care & Standards, on (03) 8699 0544 or via stephan.groombridge@racgp.org.au.

Yours sincerely

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RACGP President